QATAR UNIVERSITY

COLLEGE OF HEALTH SCIENCE

THE EFFECT OF PROTEIN SUPPLEMENTATION ON BODY MUSCLE MASS AND FAT MASS IN QATARIS POST-BARIATRIC SURGERY: A RANDOMIZED CONTROLLED TRIAL (RCT)

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ABSTRACT

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Title: The Effect of Protein Supplementation on Body Muscle Mass and Fat Mass in Qataris Post-Bariatric Surgery: A Randomized Controlled Trial (RCT)

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Background and objectives: Obesity is a chronic medical condition characterized by an accumulation of excess fat in the body that may lead to negative health consequences. Losing weight may be achieved via dietary and lifestyle modification; however, surgical options are also available with applicable criteria. Bariatric surgery (BS) has been shown to be the most effective type of interventions to achieve and sustain significant weight loss in morbidly obese people. One of the most common post-bariatric surgery complications of is protein malnutrition and micronutrients deficiency. The objective of the present study is to examine the effectiveness of protein supplementation in reducing the risk of developing protein malnutrition that lead to low muscle mass and low protein level, in post-bariatric surgery patients.

Methodology: This study is a double-blinded randomized control trial both investigators and participants were blinded to the treatment. Recruitment of participants began in March 2017 following the ethical approval of the trial (HMC IRB approval no. 16433/16). The intervention group will receive protein supplement which contain 20 g of protein and the placebo group will receive zero protein supplement every day and all participants were followed for 1 month post-surgery. The randomization was done on a weekly basis within blocks of 8 or 10 patients. Independent Sample-T Test and Paired Sample-T Test were performed to measure the effect of the intervention and the control on the study group.

Results: The mean weight loss in the control group was 9.6 kg, while the intervention group mean weight loss was 10.7 kg, with the difference between the 2 groups being statistically significant (p= 0.03). Change in muscle mass percentage was +0.50% in the placebo group, and +2.3% in the intervention group, with a P value of the difference of 0.149. Fat percentage change in the placebo group was -1.6% and -2.6% in the intervention group, with a p value of a difference of 0.153. The percentage change in Albumin in the placebo group was 2.76% and 9.71% in the intervention group, with a p value of a difference of 0.031.

Conclusion: Our study has confirmed findings from multiple studies that protein supplementation in patients post-bariatric surgery is a successful intervention for healthy and balanced weight loss. We have also found after 1 month of follow up that patients who took the treatment displayed higher level of serum albumin than those who took dietary advice alone. We have also shown trends towards significance in results of muscle and fat % change between the 2 groups and a larger sample size and a longer follow-up may further signify these results. This confirms that surgery alone cannot put an end to obesity and must be combined with well-structured nutritional education so patients do not go back to their old habits and put the weight back on.

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1. INTRODUCTION

Obesity is a chronic medical condition characterized by an accumulation of excess fat in the body that may lead to negative health consequences. It is the major contributor to some of the most prevalent chronic conditions, such as type 2 diabetes (T2D), heart and kidney diseases, metabolic syndrome, sleep apnea, and depression (National Institutes of Health (NIH), 2013; Ogden, Yanovski, Carroll, & Flegal, 2007). Obesity is the fifth leading risk factor for deaths globally, making it an extremely important public health issue (Ogden, Yanovski, Carroll, & Flegal, 2007). In 2014, a World Health Organization (WHO) report showed that more than 1.9 billion adults aged 18 years and older were overweight with over 600 million being obese (see Figure 1 for obesity classification). In addition, 44% of the diabetes burden, 23% of heart disease burden, and 7–41% of certain cancer burdens are associated with overweight and obesity (WHO, 2015). Around 2.8 million people die each year as a result of being overweight or obese. The majority of these deaths is premature and preventable and may apply an economic burden on the health systems (Reilly and Kelly, 2011).

Attempts to reverse obesity through weight loss have been the focus of the attention of many, including researchers, scientists and clinicians. This has been chiefly achieved via dietary and lifestyle modification as well as surgical approaches. Bariatric surgery (BS) has been shown to be the most effective type of approach to achieve and sustain significant weight loss in morbidly obese people (Sjöström et al., 2007). Bariatric surgery is defined as a group of surgical procedures performed to facilitate substantial

weight loss by reducing the size of the stomach and/or limiting absorption in the small intestine(American Society for Metabolic and Bariatric Surgery (ASMBS), 2017). It is considered a highly efficacious treatment for extreme obesity. However, bariatric surgery patients frequently report difficulty initiating and maintaining healthy behavioral changes following surgery (Elkins et al., 2005). Most Post-bariatric surgery patients are strictly placed on liquid diet during the early post-operative phase and are practically unable to consume large quantities of food in one sitting or taking solid protein within the first months, which put them at higher risk of developing protein malnutrition (Richardson, Plaisance, Periou, Buquoi, & Tillery, 2009).

Post-surgery multivitamin and high protein supplementation is important to avoid any nutrient deficiency (Damms-Machado et al., 2012). High protein supplements are mainly rich in protein and supplemented with vitamins and minerals. These supplements in general are inexpensive, widely distributed, and commonly used by people or patients who need nutritional supplementation while recovering from an illness or post-surgery especially post-bariatric surgery (Damms-Machado et al., 2012).

Protein supplementation is an effective approach to ensuring that post-bariatric surgery patients maintain muscle mass and healthy levels of the above-mentioned nutrients and body compositions. In the absence of this, the weight loss achieved by the surgery may present a systematic issue leading to higher fat percentage and lack of these important elements that are essential for the function of the human physiology. The imbalance of such essential body compositions and nutrient can also lead to pathological

and irreversible conditions. The objective of the present study is to examine the effectiveness of protein supplementation in reducing the risk of developing protein malnutrition that lead to low muscle mass and low protein level, in post-bariatric surgery patients.

BMI range (kg/m2)	Classification
< 18.5	Underweight
18.5 - 24.9	Healthy weight
25 -29.9	Overweight
30 - 34.9	Obesity I
35-39.9	Obesity II
= 40	Obesity III

Figure 1. World Health Organization Body Mass Index (BMI) classification for adults (Adopted from WHO Global Database on Body Mass Index, 2016)

2. LITERATURE REVIEW

2.1 Bariatric surgery indications and effectiveness

The general benefits of bariatric surgery are significant weight loss, reduced depression and anxiety, improved quality of life, and reduced mortality in patients through controlling comorbidities.

Bariatric surgery is an effective treatment for obesity, provides a long term of weight loss control, and improves obesity-related comorbid conditions (Madura & DiBaise, 2012; Nielsen et al., 2014). The main purpose of bariatric surgery is to reduce overall mortality and resolution or marked improvement of debilitating chronic conditions such as hypertension, diabetes, hyperlipidemia, obstructive sleep apnea, and obesity - thereby prolonging life expectancy and improving quality of life (Arterburn & Courcoulas, 2014).

Bariatric surgery is a group of procedures, which facilitate weight loss by reducing the food consumption of an individual after surgery. Three main bariatric surgery procedures include gastric bypass, gastric banding and sleeve gastrectomy. According to American Society for Metabolic and Bariatric Surgery (ASMBS) (2017), gastric bypass is the most common. It involves re-routing of digestive system past the stomach to enhance satiety. For gastric band procedure, an inflatable band is placed on the top of the stomach to create a small stomach pouch which restricts the amount of food that can be eaten and reduces feelings of hunger by pressing on the surface of the

stomach. Sleeve gastrectomy removes 80% of the stomach to create a small stomach pouch, which also reduces food consumption (Whiteman, 2013). (Figure 2. Types of bariatric surgery)

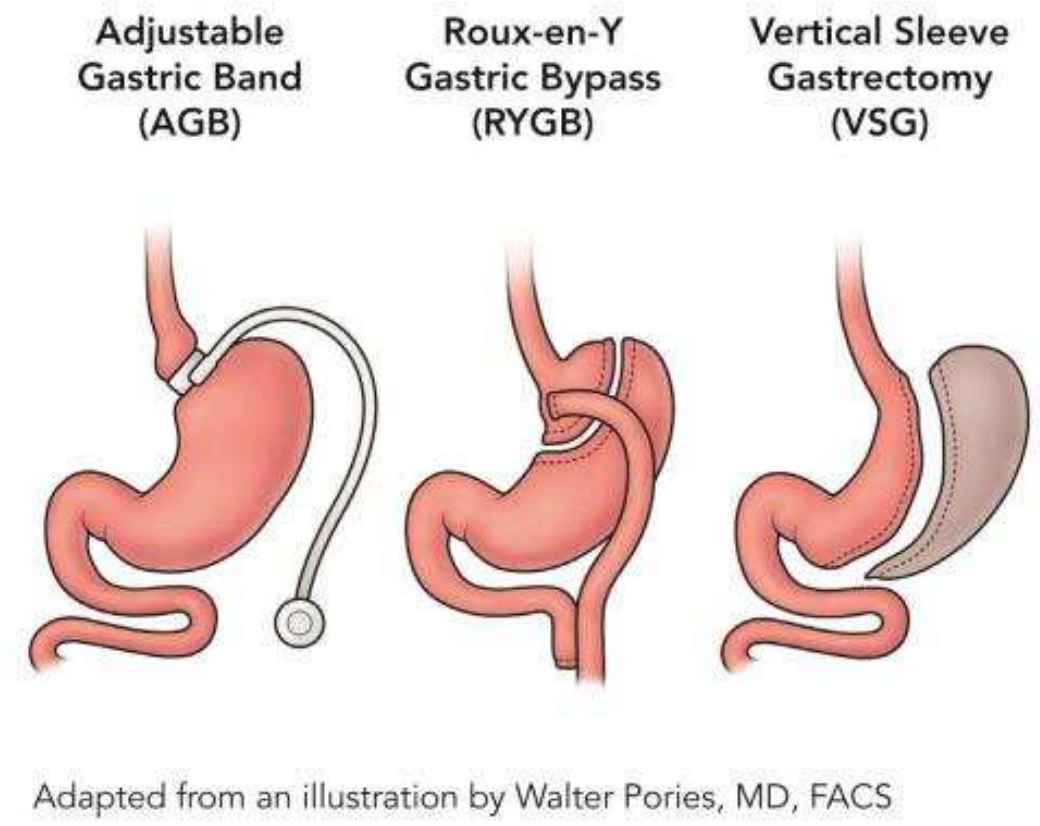


Figure 2. The 3 main types of bariatric surgery used to reduce obesity
(Adopted from Bariatric Surgery and the Endocrine System Fact Sheet by Morton and Salehi, 2012)

Based on the National Institute for Health and Excellence (NICE) guideline published in 2006, bariatric surgery is recommended as a treatment option for people with morbid obesity: if they have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other comorbidities such as type 2 diabetes or high blood pressure that could be improved if they lost weight; all appropriate non-surgical measures have been unsuccessful; and should be a part of a comprehensive package provided by a specialist team. It is also recommended as a first-line option for adults with a BMI of more than 50 kg/m2 in whom surgical intervention is deemed appropriate (NHS NOO, 2010).

Bariatric surgery procedures have shown greater improvements in terms of weight loss outcomes with lesser occurrences of weight comorbidities regardless of the type of procedure when compared to non-surgical interventions. This was based on a twenty-two trials done with 1798 participants included followed up from one to two years for measures of weight change after surgery. Improvements for some aspects of health-related quality of life, such as physical activity and healthy behavior, were noted (Colquitt, Pickett, Loveman, and Frampton, 2014).

Studies show significant decrease in weight and hemoglobin A1c (HbA1C) at 2 years in patients with T2D previously treated with BS, showing good gastrointestinal tolerance (Gorgojo-Martínez, Feo-Ortega, & Serrano-Moreno, n.d.). Also Bariatric surgery can lead to a modest reduction in clinical depression over the first post-operative years (Luppino et al., 2010). Systematic reviews and meta-analyses of the effectiveness and risks of bariatric surgery showed a profound reduction in weight with low mortality

outcomes associated with surgery (Colquitt, Pickett, Loveman, and Frampton, 2014;Arterburn& Courcoulas, 2014). Although mortality rates for post-bariatric surgery patients have decreased significantly and are now similar to those of cholecystectomy or appendectomy in bariatric centers with high surgical volumes, however, the early and late rates of adverse events associated with bariatric surgery are still problematically high at 17% (Chang et al., 2014).

With bariatric surgery's exceptionally low mortality rate, it was considered remarkable because more lives were improved considering the life-threatening effects of obesity on patients before the surgery. Thus, the benefits brought by bariatric surgery to its patients exceeded the risks (American Society for Metabolic and Bariatric Surgery (ASMBS), 2017). Studies showed at least 90 percent of people with severe obesity who undergone bariatric surgery have been successfully maintaining at least 50 percent body weight loss after surgery, and more than 80 percent of those with very severe obesity managed maintain at least 50 percent excess body weight loss (Schollenberger, 2016). Effect of bariatric surgery not only improved health and longevity but also the quality of life of the individual. It has positively enhanced the individual's self-esteem, social interactions, work and sex drive, and has reduced depression and anxiety (ASMBS, 2017).

Obesity is one of the greatest health problems in Qatar. More than 70% of Qatar population is either obese or overweight and nearly half of all men are obese (Qatar Biobank Annual Report, 2016). Bariatric surgery service has started at HMC in 2011 to

meet the growing demand for weight loss surgery due to obesity is endemic in Qatar.

In February 2011, HMC took the decision to recognize Bariatric Surgery as an independent service. This was done for a number of reasons and mainly amongst the reasons are: 1) to improve the care patients receive at HMC and to bring it to the highest international standards, 2) to deal with the obesity endemic in Qatar.

Following the guidelines from Supreme Council of Heath Qatar, the national bariatric guidelines indications for surgery are as follows:

1, Patients with a BMI >40 kg/m2 without coexisting medical problems and for whom bariatric surgery will not be associated with high risk.

2, Patients with BMI ≥35 kg/m2 and one or more severe obesity related co-morbidities.

3. Patients with BMI of 30-34.9 kg/m2 with uncontrolled type 2 diabetes or metabolic syndrome may also be offered a bariatric procedure if approved by multidisciplinary team decision (Qatar National Bariatric Guidelines Supreme Council of Heath Qatar, 2016) (Appendix D).

2.2 Post-bariatric complications

Whatever the bariatric procedure, there is a need for routine nutritional screening, recommendations for appropriate supplements and monitoring compliance (Ziegler, Sirveaux, Brunaud, Reibel, and Quilliot, 2009). For the three most common procedures, including adjustable gastric bands (AGB), sleeve gastrostomy (SG) and roux-en-Y gastric

bypass (GBP), iron deficiency is common especially in menstruating women mainly as a consequence of nutrient deficiencies (Jáuregui-Lobera, 2013). GBP, for instance, is associated with greater deficiency risks from calcium, vitamin D and vitamin B12, in comparison with other types of bariatric surgeries. Being deficient in vitamins and minerals leads to serious complications such as encephalopathy or protein-energy malnutrition (Ziegler, Sirveaux, Brunaud, Reibel, and Quilliot, 2009).

Gastric bypass surgery makes stomachs smaller and it changes the way body handles the food taken. Because one eats less food, the body cannot absorb all the calories from the food eaten and it misses on the absorption of some important vitamins and minerals. Thus, it is recommended to take vitamins and minerals to support the body's optimal well-being.

Bariatric surgery complications may develop if the patients do not follow the instruction of taking medication or supplement. After surgery the incidence of vomiting, nausea or different food intolerances may further increase the risk of post-surgery complications (Karmali et al., 2010; Moize et al., 2003). Unfortunately, patient deficiencies result from inadequate calorie or food intake that is associated with macro and micro nutrient mal-absorption.

One of the common post-operative deficiencies or complications of bariatric surgery is protein malnutrition caused by inadequate protein intake. Protein is the most important nutrient in the post-bariatric diet. Studies show that it plays a significant role in body weight regulation (Griffith, Birch, Sharma, and Karmali, 2012). These kinds of

surgeries work to restrict energy intake mainly to reduce body weight but on other side it may lead to insufficient protein intake, protein absorption, and excess loss of lean tissue (Moize et al., 2003). Nutrition supervision is one of the very important sides for post-bariatric patients because it may lead to many predicaments such as malnutrition, vitamin, micro- and macronutrient deficiencies that can lead to deleterious consequences (Damms-Machado et al., 2012; Friedrich et al., 2013).

Laparoscopic Roux-en-Y gastric bypass (LRYGB), which is a standard bariatric surgical procedure, presents excellent long-term results, but it is also associated with clinically late complications, which develop over the long term in post-operative bariatric patients. These include weight gain and nutritional deficiencies (Griffith, Birch, Sharma, and Karmali, 2012). After the bariatric surgery procedure, weight gain occurring about 10% of patients after 5 years and in about 20% of patients after 10 years (Christou, Look, and Maclean, 2006), the cause of which maybe multifactorial such as "lack of control over food urges, addictive behaviors, decreased overall postoperative well-being, lack of self-monitoring and fewer postoperative follow-up visits"(Odom, Zalesin, Washington, et al., 2010). Moreover, nutritional problems after bariatric surgery occur due to decreased food intake or low physical activity, reconfiguration of GI motility and enzymatic changes. Other complications that arise are anemia, which is estimated to occur in 20%-49% of patients after surgery due to iron, folate and vitamin B12 deficiencies (Lopez, Patel, and Koche, 2007). They are likewise deficient in magnesium, zinc, calcium, 25-hydroxyvitamin D, thiamine and β-carotene (Lopez, Patel, and Koche, 2007; Toh et al.,

2009; Dalcanale, Oliveira, Faintuch, et al., 2010).

According to Misuari Bariatric Services (2016), zinc deficiency has been reported in 36% of gastric bypass patients while magnesium deficiency is rare. Zinc, as an antioxidant nutrient necessary for protein synthesis, is recommended for gastric bypass patients to take a multivitamin with 100% of the daily value for zinc or 40 to 60 mg of zinc twice a day for once month should deficiency develop ed. For magnesium intake, gastric bypass patients should take up to 300 mg of magnesium per day to correct deficiency.

2.3 Importance of protein post-surgery

The major macronutrient deficiency after bariatric surgery is protein malnutrition (Bal et al., 2012).Strategies for successful weight loss or weight reduction after bariatric surgery is the purpose of reducing body fat mass (FM) while minimizing reductions in lean tissue mass (LTM) which is significant for body health status (Friedrich et al., 2013). A protein-rich diet make a person feel satiated, and thereby the consumption will be low in overall energy intake (Westerterp-Plantenga, Nieuwenhuizen, Tomé, Soenen, & Westerterp, 2009).

Post-bariatric medical guidelines for the nutritional support recommend an average daily protein intake (PI) of 60-80 g or 1.1 g/kg of ideal body weight (IBW) after surgery to reduce an undesirable post-surgical excessive loss of LTM(Mechanick et al., 2009; Snyder-Marlow, Taylor, & Lenhard, 2010). Continuing the proper daily intake of protein can be challenging for post-bariatric patients, as explained above. Subsequently,

reduction in blood protein levels, and finally in muscle mass has to be expected(DeLegge & Drake, 2007). As previously mentioned, micronutrient deficiencies are common in obese patients, and can occur in both the pre and post-operative settings(Shankar, Boylan, & Sriram, 2010).

2.4 Optimal post-bariatric surgery care

In post-bariatric surgery diet, protein is a cornerstone because it serves as the building block of muscles. It becomes very important during post-bariatric surgery because proteins are constantly being broken down and needed to be replaced continuously. Being deficient in protein lacks the necessary body nutrient to rebuild muscle, which is important in having good health and weight loss (Rogers, 2016).

According to American Society for Metabolic and Bariatric Surgery (ASMBS, 2017), bariatric surgery can give long-term positive health and weight loss outcomes when given good aftercare and observe good lifestyle. ASMBS (2017)has specific recommended doses, such as having at least 64oz of fluids a day to prevent dehydration, constipation and kidneys stones. Daily supplements are also required such as multi-vitamins, vitamin D, calcium, iron and vitamin B12. Moreover, patients who undergone bariatric surgery are advised to take protein-rich foods, with 60-100g daily depending on the medical conditions, operation type and level of activity. It is likewise advised to limit consumption of carbohydrates up to 50 grams per day to avoid weight regain.

Many studies indicate a significant reduction in lean body mass and decrease in levels of albumin and pre albumin resulting from protein deficiency after bariatric

surgery. Adequate protein in the patient diet is important as it is the main reason the influences body composition after surgery and also, minimizes the occurrence of losing muscle mass (Damms-Machado et al., 2012; DeLegge & Drake, 2007; Moize et al., 2003).

2.5 Needs for protein supplement

Protein supplement is important for patients who have undertaken bariatric surgery. The mechanism why patients do better with high protein supplement are somewhat unclear and is likely to be multifactorial, with several components of the supplement contributing to better effects (Arterburn & Courcoulas, 2014). It might facilitate weight loss, especially body fat loss, and work against muscle mass wasting (Lejeune, Kovacs, & Westerterp-Plantenga, 2005). After bariatric surgery, long-term follow-up focuses mainly on weight loss maintenance, blood value and adherence to aftercare recommendations regarding micronutrient supplementation (Elkins et al., 2005).

For all post-bariatric patients remedial measures should be undertaken before any significant lean body mass loss occurs. It is important that dietary sources of protein are the first food choice for post-bariatric patients. Oral intake (high protein sources) and a high-protein formula or supplement as the first step must be encouraged to increase protein level intake. If the patient cannot take high protein food, he/she will be taking the protein supplements. This is often difficult in obese patients who are trying to lose weight especially in first stages of diet when they can't tolerate meat products(Schweiger, Weiss,

& Keidar, 2010).

Weight loss that occurs from losing muscle instead of fat will happen for post-surgery patients and that is considered undesirable outcome. Subjects need to work against developing chronic protein deficiency. If it is not possible for them to meet protein requirements through diet then protein supplements should be considered (Thorell, 2011).

High energy levels from dietary protein restrict increase in body weight through its satiety and energy inefficiency related to the change in body composition. In the short term, protein is more satiating than carbohydrate. An increase in protein consumption significantly lowers body weight regain after weight loss. The positive effect of high-protein diets on body weight loss was evident only under ad-libitum energy intake conditions (Westerterp-Plantenga, 2003). However, the consumption of protein greater than two to three times the U.S. Recommended Daily Allowance contributes to urinary calcium loss and may, in the long term, predispose to bone loss. Caution with these diets is recommended in those individuals who may be predisposed to nephrolithiasis or kidney disease, and particularly in those with diabetes mellitus (Eisenstein, Roberts, Dallal and Saltzman, 2002). A high protein diet shows a reduced energy efficiency related to the body-composition of the body-weight regained which favors fat free mass (Western-Plantenga, 2008).

Protein-induced diets having all essential amino acids exhibit higher increases in energy expenditure than low-protein diets. Both in young and elderly adults, there was no

adverse effects observed on net bone or calcium balance in consuming protein-induced diets. Protein-rich diet is particularly helpful to individuals with obesity and metabolic problems and with type 2 diabetes (Westerterp-Plantenga, Nieuwenhuizen, Tome, Soenen, and Westerterp, 2009). Low-carbohydrate or high-protein diets are beneficial for weight loss, increased satiety and better metabolic parameters (Kushner and Doerfler, 2008)

A diet with low-glycaemic index-low-fat-high-protein has unique beneficial effects compared with the conventional American Heart Association (AHA) diet for the treatment of the atherogenic metabolic risk profile of abdominally obese patients, as shown by the favorable changes in the metabolic risk profile noted such as decreases in triacyglycerols, lack of increase in cholesterol. High-density lipoproteins (HDL)-cholesterol ratio, increase in low-density lipoprotein (LDL) particle size (Dumesnil et al., 2001).

Evidence suggests that meals with higher protein content increase the chance of weight loss and fat loss as compared to low-protein diet. In dietary practice, it is recommended to partially replace refined carbohydrate with protein sources which contains lower saturated fat (Halton and Hu, 2004).

The importance of protein supplementation in bariatric patients was underscored as it was found to be effective in achieving the recommended daily protein intake among bariatric patients. With 101 patients undergoing laparoscopic gastric bypass (LGBP) or laparoscopic sleeve gastrostomy (LSG), weight loss and male gender had significant

association with loss of fat free mass ($p < 0.001$) (Andreu, Moize, Rodriguez, Flores and Vidal, 2010).

Patients who undergone bariatric surgery need to adhere to a special dietary recommendation to achieve weight loss goals and maintenance. Literature reviews conducted showed postoperative consumption of protein being linked to induction of satiety, weight loss and nutritional status. A protein-rich diet can help increase satiety, enhance weight loss, and improve body composition (Faria, Faria, Buffngton, de Almeida Cardeil, Ito, 2011).

The role of protein in weight management was highlighted by Noakes (2008). Studies on a higher protein pattern have shown improvements in body composition despite similar weight loss. Protein intake and exercise were associated with improved lean mass retention. Enhanced satiety, as an important factor in weight loss, studies revealed that high protein meals and foods are more satiating than high carbohydrate or high fat meals based on some sensory ratings done (Noakes, 2008).

Since post-operative bariatric patients are at risk of protein deficiency, a study to determine possible benefits of postoperative protein supplementation weight reduction, body composition, and protein status was conducted by Schollenberger et al. (2016). Twenty obese patients who underwent bariatric surgery were randomly assigned to a daily protein supplement over 6 months and to the control group given with isocaloric placebo in a double-blind fashion, where protein intake, energy intake, body weight, body composition, blood proteins, and grip force were collected prior to intervention at 1, 3,

and 6 months after operation. Results showed that body composition is improved by protein supplementation through increased loss of body fat mass and reduced loss of lean body mass within the 6 months follow up (Schollenberger et al., 2016).

2.6 Whey and Leucine supplementation

In a double-blind randomized controlled trial, the effect of a high whey protein (leucine) and vitamin D-enriched supplement on muscle mass preservation during intentional weight loss in 80 obese older adults showed that appendicular muscle mass was preserved than using isocaloric control diet, without significant difference between the two groups in terms of muscle strength and function which improved overtime. This supplementation reduces risk of sarcopenia by preserving lean muscles in the elderly (Verreijen et al., 2015).

A 13-week intervention of leucine-enriched whey protein and vitamin D oral nutritional supplement resulted in improvements in muscle mass and lower-extremity function among sarcopenic older adults. This proves that nutritional supplementation alone could positively improve sarcopenia and prevent mobility disability especially among geriatric patients who are unable to exercise (Bauer et al., 2015).

A meta-analysis conducted related to leucine-rich protein supplementation in the geriatric population on its effects on anthropometrical parameters and muscle strength showed that leucine supplementation has beneficial effects on body weight, body mass index, and lean body mass especially those subjects already prone to sarcopenia. When

compared to control groups, leucine supplementation significantly increased gain in body weight ($p=0.02$), lean body mass ($p=0.0005$), and body mass index ($p=0.001$). Leucine-rich protein supplementation was more effective in the participants manifesting sarcopenia in terms of body weight and lean body mass (Komar, Schwingshackl and Hoffman, 2015). Similarly, leucine supplementation increases the muscle protein fractional synthetic rate and therefore is beneficial to age-related decline in muscle mass especially in elderly individuals (Xu, Ta, Zhang, Gui, and Yang, 2015).

Individualized, nutrient-rich diets within current nutritional guidelines for weight control can be recommended by medical practitioners. Diets with moderately increased in protein and restriction in carbohydrate and fat intake are beneficial on body weight, body composition, and associated metabolic parameters. However, long-term compliance and safety of chronic high-protein intake should be observed (Brehm and D'Alessio, 2008).

Utilization of specific protein such as whey protein provides a physiologically functional food component for body weight regulation and reduction which contributes to regulating food intake by increasing satiation through whey protein fractions, bioactive peptides, amino-acids released after digestion, and combined action of whey protein and/or peptides and/or amino acids with other milk constituents (Luhovyy, Akhayan, and Anderson, 2007).

Greater weight losses are given by diets high in protein, but either low or modest in carbohydrate, than traditional low-fat diets. It is the protein, and not carbohydrate, content that is important in promoting short-term weight loss which is an effect from

increased satiety. This evidence indicates that protein should contribute 25% to 30% of energy intake, moderate in carbohydrate (35% to 50% of energy) and in fat (25% to 35% of energy) (Schoeller and Buchholz, 2005).

3. AIM AND OBJECTIVES

3.1 Aim:

The aim of this study is to assess the effectiveness of protein supplementation in reducing the risk of developing protein malnutrition that leads to low muscle mass and low serum protein level, in post-bariatric surgery patients.

3.2 Objectives:

The specific objectives of our study are to assess changes in the following health parameters at 1 month of the trial:

1. Muscle and fat mass.
2. Body Weight.
3. Protein (Albumin and total protein).
4. Vitamin B12
5. Magnesium and Zinc.

4. RESEARCH QUESTIONS

1. What is the difference in change of muscle and fat mass between participants who received protein supplement and those who received the placebo?
2. What is the percentage of weight reduction in the intervention in comparison with control group?
3. What is the difference in protein level (albumin/ total protein) in post-bariatric patients receiving intervention compared with control group?
4. What are the changes in Vitamin B12, Magnesium and Zinc in the intervention group in comparison with the control group?

5. HYPOTHESIS

We hypothesized that post-bariatric surgery patients receiving protein supplement will develop the following at the end of the trial (compared with those receiving zero protein supplement):

1. Lower fat mass
2. Higher muscle mass
3. Higher percentage of weight reduction
4. Higher serum protein levels
5. Higher levels of Vitamin B12, Zinc and Magnesium

6. METHOD

6.1 Study design

This study is a double-blinded randomized control trial. Both investigators and participants were blinded to the treatment (intervention and placebo products were identical and unlabeled). The research recruited participants in March 2017 and following them up for 1 month. The randomization was done on a weekly basis within blocks of 8 or 10 patients. This was roughly the number of patients available per week.

In this RCT simple randomization process was used to assign patients to either groups- intervention & placebo. Using a computer generated random list, the treatment and the placebo were allocated in a random manner to numbers that label individual patients.

Both the intervention and control groups received standard dietary instructions in post-bariatric surgery period including hospital stay (1-2 days) and 1 month after. The intervention group received protein supplement and the placebo group received zero protein supplement everyday over 1 month after surgery. The placebo & the protein supplement slightly differed in the caloric (the difference is 150 kcal/bottle) content. Although this difference was not clinically significant, this issue was addressed as a limitation for this study.

Investigators and researchers, including providers of care (dietitian and rehab

staff) in this study were blinded to the intervention, i.e. they were not aware of who was on protein supplement and who was on placebo. Patients were also blinded to the intervention, i.e. they did not know whether they are taking protein or zero protein supplement. For the blinding, a dietician did assign the treatment and the control to patients as per the above randomization results. This dietitian was also responsible for filling the intervention & control ready-to-feed shakes into identical bottles labeled either A or B. The dietician did not have any other responsibility such as data entry or follow up of participants as this was done by the PI and research team; he was only responsible for the blinding process. Un-blinding was unlikely within the settings of our trial, however, any suspicion of un-blinding was dealt with appropriately and may result into the cessation of participation in the trial.

6.2 Study participants

The recruitment of participants for this RCT was based at Hamad General Hospital. Patients who underwent bariatric surgery and fulfill our inclusion criteria were randomized to either the intervention or the control arm of the study. The catchment area for Hamad General Hospital can include the entire Doha district and the surrounding metropolitan area. However, admission to the hospital may also include other regional areas, thereby making the sample of our population representative of the entire Qatari population.

6.3 Sample size

The study population was bariatric patients admitted to bariatric department for surgery based on their eligibility criteria (BMI≥35). All patients were enrolled in the study prior to admission and were then given the intervention or the placebo on the first day post-surgery. A total of 42 obese Qatari adults from Bariatric and Metabolic Center in Hamad General Hospital (HGH), who fulfill HGH entry criteria for bariatric surgery, were enrolled in this experimental study. This was subject to availability and time constraint for the purpose of this thesis. However, a statistical advice provided suggested that the number obtained is sufficient for the purpose of the trial.

Using the primary outcome estimates available in the published study (Schollenberger, A E et al; 2016); body fat mass (BFM) and lean body mass (LBM) (kg) in the intervention group at baseline and 3 months (BFM baseline 78.2±19.1 and 3 months 59.9±15) and (LBM baseline 65.2±14.2 and 3 months 58.2±10.6) compared with Placebo group (BFM baseline 68.2±12.0 and 3 months 53.9±11.5) and (LBM baseline 68.9±13.4 and 3 months 62.2±11.3) and with 90% power and a type I error rate of 5%, the required sample size would be 70 participants (35 in each group), however, to compensate for possible dropouts, non-response and loss to follow-up it would be good to increase additional 15% to 20% in calculates sample size (a total of 80 participants i.e., 40 in each group). The only difference between the above study population and the population of our RCT is that the German study population was more obese (BMI between 49 and 52). Both studies looked at the effect of protein supplementation on

muscle and fat mass in post-bariatric surgery patients.

6.4 Inclusion criteria:

Study participants had the following criteria in order to participate in the trial:

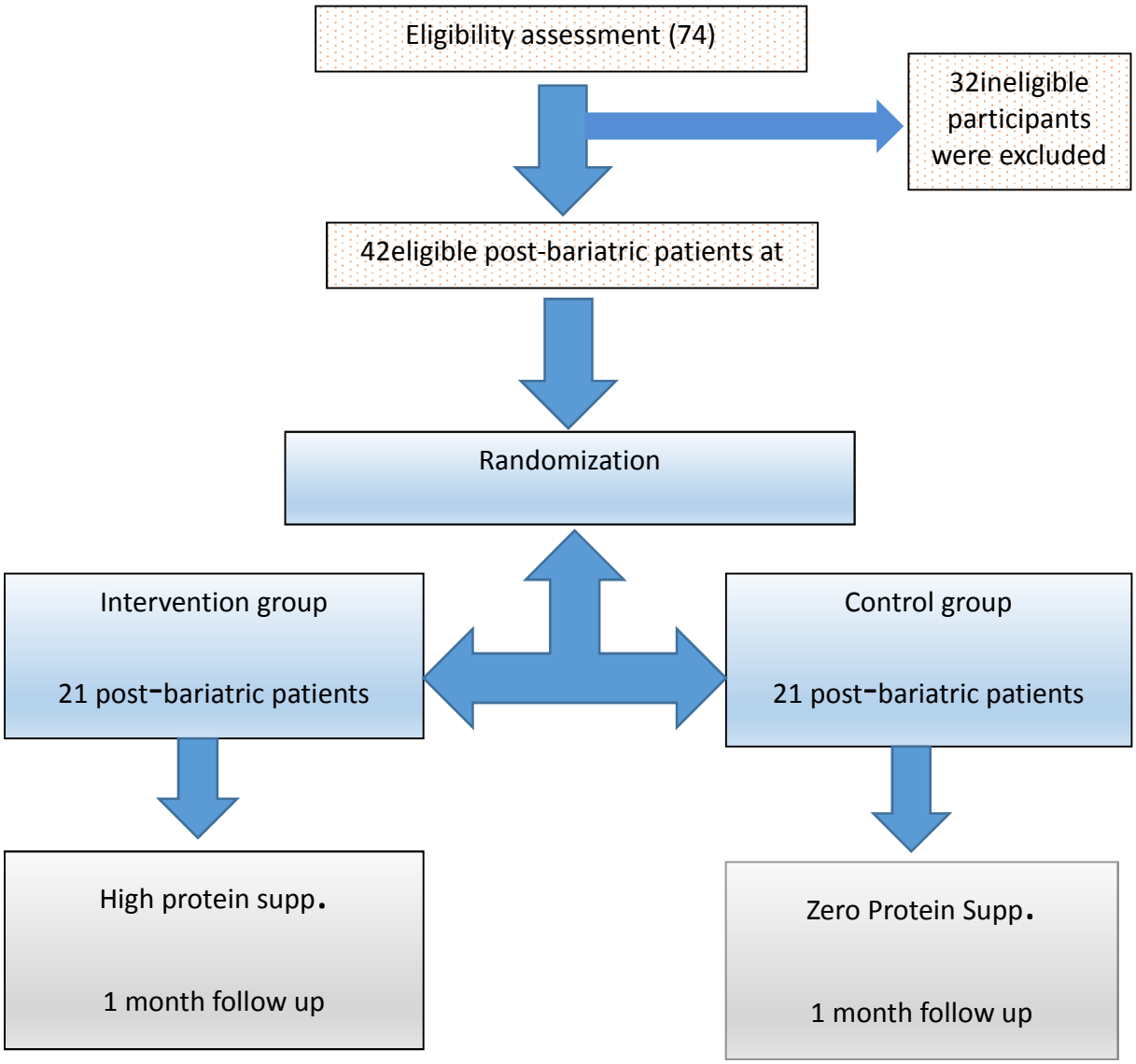
1. Qatari males or females.
2. Aged between 18 and 60 years
3. Based at the bariatric surgery list of HMC with their follow up scheduled be at HMC (see appendices).

6.5 Exclusion criteria:

Patients were excluded from participating in the trial if they have the following criteria:

1. Any Renal or liver disease because that will affect protein or albumin level in body.
2. Past history of bariatric surgery (Gastric Band & Gastric bypass)
3. Patients will be further excluded after starting the trial if they did not take at least 80% (minimum 24 bottles) of their allocated intervention or placebo products throughout the trial.

6.6 Study flow chart (Figure 3)



6.7 Intervention and control

6.7.1 Intervention

1. Patients received nutritional counseling by a bariatric dietitian as a routine standard of care, which included strictly fluid diet for the first months. This educational component applies to all post-bariatric surgery patients at discharge. (Appendix G).

2. Before discharge from the hospital, patients were provided with the supplement and were advised by the dietitian regarding its use (one can per day, over 3-5 intervals, i.e. the bottle will be used over the entire course of the day through a number between 3 and 5 shots/doses).

3. Each supplement (bottle) contains 20 g of protein, 250Kacl plus different micronutrient and macronutrient, per 200 ml can (Cubitan,Protein, Nutricia, Netherlands), (appendix E).

6.7.2 Control (placebo)

1. Patients received nutritional counseling by a bariatric dietitian as a routine standard of care, which included strictly fluid diet for the first months. This educational component applies to all post-bariatric surgery patients at discharge. (Appendix G).

2. Before discharge from the hospital, patients were provided with the supplement (placebo)andwere advised by the dietitian regarding its use (one can per day over 3-5 intervals).

3. Following hospital discharge, Control patients received supplement which contains 0g

protein, fat free, 100 kcal and enriched with electrolytes, per can (200 ml) (preOp, Nutricia, Netherlands), (appendix F).

Note:

a. Both groups were instructed to take one supplement pack through the day in equally divided portions, and, they should store it in room temperature and drink it without heating.
b. Giving high protein supplement is an optional routine practice for post bariatric surgery patient at HGH, making this practice a predictable approach to our participants.

6.8 Materials

The protein supplement, which is a standard practice, adopted by HMC for post-bariatric surgery patients, consisted of whey protein isolate with the following characteristics:

- Pure Whey Protein Isolate
- Whey protein isolate is the most pure and concentrated form of whey protein available
- Whey protein isolate contains higher protein content (90-95%) and less lactose (less than 0.5%). It is a complete protein with all the indispensable essential amino acids and is an exceptional source of branch chain amino acids (BCAAs), especially leucine necessary for tissue growth. Whey protein is a soluble, easy to

digest protein and is efficiently absorbed into the body (Marshall, 2004).

- Aside from amino acids, other biological components of whey protein include lactoferin (concentration is commonly 0.35-2.0 percent of total proteins), immunoglobulins (10-15 percent of total whey proteins), lactoperoxidase (accounts for 0.25-0.5 percent of total protein in whey), glycomacropeptide (with 10-15 percent), and bovine serum albumin (10-15 percent of total whey protein). These bioactive components, the essential and non-essential amino acids help improve body mass index especially in individuals doing exercise programs, by enhancing muscle mass and reducing fat mass. (Marshall, 2004).
- It contains (per 200 ml can) 20 g of protein, 250Kacl plus different micronutrient and macronutrient.
- The zero protein supplement contains 0g protein, fat free, 100 kcal and enriched with electrolytes, per can (200 ml).

6.9 Measurements

1. Baseline measurement of body composition (fat mass and muscle mass), height and weight were conducted on day one of the trial, using Tanita body composition instrument and other physical body measures.
2. Baseline blood test for total protein, albumin, Vit B12, Zinc and Magnesium levels were collected.

3. All of the above measurements were repeated at the end of the follow up period (1 month).

*Note: all of the above measurements and the collection of blood sample is routine practice for post-bariatric surgery patient.

6.10 Study visits

Patients follow up visit was after 1-month post-surgery at the Bariatric Dietician Clinic in OPD department at HGH, and covered the following:

A. Post-surgery dietary advice, to sustain a hypo caloric and protein-rich diet.
B. Anthropometric parameters for body composition (see below).
C. All patients were followed up through weekly phone calls to ensure compliance and adherence to the study protocol. Questions such as "how many bottles of supplements are left?" Or, "how many bottles have you had so far?" were asked.
D. Collection of blood sample after an overnight fasting. All blood markers were measured and calculated in the central laboratory at HGH.
E. Patients were asked about their supplement intake compliance to determine their eligibility to be part of the study (see exclusion criteria).

*Note: Collection of blood sample after 1 month is a routine practice for post-bariatric surgery patient at HMC

6.11 Body composition (BC)

The measurements of anthropometric data took place following overnight fast, patients wearing light clothes and barefoot (baseline and 1 month follow up). Tanita's body composition analyzer provides precision in estimating body composition including Weight, Body Fat Percentage, Body Fat Mass, Body Mass Index (BMI), Fat Free Mass, and Estimated Muscle Mass and percentage. However, Height was measured using a fixed wall stadiometer, both inter- and intra-reliability testing was conducted prior to the trial to ensure consistency of the measures across the study population. The results of these tests were satisfactory thereby ensuring that the assessment tools produced consistent and reliable measurements.

All these data were assessed using TanitaHealthWare software that is specific program to analyze body composition.

6.12 Blood sample

Blood samples were collected from patients in (HGH) laboratory at baseline and 1 month following an overnight fast. Complete blood count (CBC) was used. Total protein, serum Albumin, zinc, magnesium and vitamin B12 were also assessed. The laboratories of HGH are internationally accredited laboratories that follow international standards.

6.13 Data collection and handling:

All data obtained from this study were collected by the principal investigator and were saved in a secure location where only the project supervisors and a statistician have access. Data were de-identified during and post collection to ensure privacy and ethical protocols are followed. All data were stored and kept safe for a period of time according to HMC policy and remain a property of HMC and the actual physical location of any electronic copies was also be at HGH. Confidentiality of patients was highly maintained throughout the trial.(appendix C).

7. STATISTICAL ANALYSIS

Data analyses were performed using the statistical software SPSS package 20. The main aim is to analyze Body composition and other anthropometric changes throughout follow up. The normality of the variables was assessed by the Kolmogorov-Smirnov test. Characteristics and demographics of participants were summarized, based on the assignment of treatment or placebo, using means and standard deviations (SD) for quantitative variables. Baseline data for the two groups were compared using two tailed independent samples t-tests. The P value for the difference between the 2 groups for each variable was also provided. A baseline analysis of all data for the 2 groups was performed using independent t-test with a p-value of the difference. During the follow-up, changes in weight, body fat percentage, muscle mass, total protein level, albumin level, vit B12, Zinc and Magnesium were compared within groups using paired t-test and between

groups using independent sample t-test. A linear regression model was also used to check if variables such as age and gender would confound the results. Other fundamental confounders such as diet intake were not incorporated into the multivariate binary regression model, mainly because post-bariatric patients within the 1st month are both unable and not allowed to take any solid foods and few specific liquid foods such as milk and soups are recommended to them by the dietician. All patients are trained to follow such diet. Moreover, being an RCT, it is expected that all confounders (including hidden confounders) are balanced between the 2 groups and no assessment of baseline variables such as diet, physical activity and any other biological differences between the 2 groups is required. This is consistent with the CONSORT statement for RCTs.

8. ETHICAL CONSIDERATIONS

The following ethical issues were taken into consideration during the trial:

1. Patient has the right to refuse participating in the study.
2. Patient has the right to withdraw from the study in any time.
3. This was clearly explained to all patients in the "patient consent form" that patients were asked to sign as an agreement to enter the study (Appendix A).
4. Researchers and other health-care professionals held all information about patients in strict confidence and disclose it only to those who have a legal right to this information. Moreover, the visits were in private rooms to take patients measurements.

5. Omitting information that might lead to the identification of individual subjects, limiting access to the information.
6. De-identification of data and confidentiality of patients were highly maintained throughout the trial
7. Intervene to protect patients if researchers are highly suspicious that a risk or abnormal lab value is imminent, and if sufficient expertise and experience to Interpret the situation is not present, staff will seek advice from more experienced professionals.
8. Within the time if there is any significant progression in value or intervention group, in this case no need to continue the study.

Ethical approval request was requested from both HMC and QU IRB committees. Both committees granted the approval thereby confirming the legitimacy of our study. The RCT approval number from HMC is 16433/16(Appendix B)

Also, we have conducted an RCT to confirm the effectiveness of protein supplementation for post-bariatric surgery patients as a means to retain muscle mass so retention of protein. Although the protein supplementation is currently used by HMC, it is not a standard procedure and requires evidence-based research to help adopting this as a standard treatment. This and other ethical issues have been presented to the HMC IRB, which has subsequently approved the trial.

9. BUDGET

All supplementation materials were provided by the Department of Bariatric and Metabolic Surgery at HGH. The department also provided staff assistance and services. Therefore, there is no need to apply for budget for this project.

10. CLINICAL TRIAL REGISTERATION

Our clinical trial was registered with *ClinicalTrials.gov* (US-NIH) PRS (protocol registration and results system) with an ID number: 16433.

11. RESULTS

Baseline results:

Baseline characteristics and anthropometric data for all participants are summarized and presented in Table 1. A total of 74 participants were screened over the period of the study recruitment with 32 being ineligible due to inclusion and exclusion criteria (inclusion and exclusion criteria sections 6.3 and 6.4). Forty-two participants were randomized into either the placebo group or the protein supplementation group (treatment) to evaluate changes in weight, body fat percentage, muscle mass, total protein level, albumin level, Vit B12, Zinc and Magnesium between baseline and 1 month follow up (Figure 1).The majority of participants in the study were females (30 females and 12 males) with equal numbers of males and females in the 2 groups (15 females and 6 males per group). All individual variables were compared between the 2 groups using an *independent t-test*and no statistically significant differences, apart from BMI, were found between the intervention and the placebo groups at baseline (Table 1).

There was a small but statistically insignificant difference in the mean age of participants in the 2 groups [Intervention group: mean age ± (SD) = 33 ±(12.9) and the placebo group: mean age ± (SD) = 35.2 ± (9.6), p =0.528]. there was no significant difference in height [162.2 ± (9.4) and 162.7 ± (7.8), p= 0.8598], however, participants in the intervention group had higher but not statistically significant mean weight in comparison with the placebo group [120.7 ± (20.1), vs 109.6 ± (91.3), $P \leq 0.074$]. All other variables to be assessed in this trial were compared and no significant differences

were found between the placebo and the intervention groups (Table 1).

All variables were assessed for normality at baseline using Kolmogorov-Smirnov test to validate the use of linear regression models.

Follow up (1 month) results:

Change in weight, BMI, muscle and fat mass percentage:

Table 2 demonstrates the changes and % changes in weight, fat mass % and muscle mass % from baseline to 1 month follow up within the one group (treatment and control) and between the 2 groups. The placebo group mean weight loss in the control group was 9.6 kg, $p \leq 0.001$, while the intervention group mean weight loss was 10.7 kg, $p \leq 0.001$, with the difference between the 2 groups being statistically significant ($p= 0.03$). the BMI was very similar with the placebo group losing 9.5 kg/m2, $p \leq 0.001$, while the intervention group BMI loss was 11.6 kg/m2, $p \leq 0.001$ and the difference between the 2 groups being statistically significant ($p \leq 0.001$). Change in muscle mass percentage in the placebo group has been 1.59, $p= 0.676$ and 12.78, $p \leq 0.001$ in the intervention group with the difference between the 2 groups not being statistically significant ($p= 0.149$). Fat percentage change in the placebo group was 3.39, $p= 0.008$ and 7.74, $p \leq 0.001$ with the difference between the 2 groups not being statistically different ($p= 0.153$).

Change in total protein and albumin:

Table 3 demonstrates the change in the outcome of total protein and albuminpercentage at 1 month. The placebo group % change of total protein was 0.88, p= 0.597 while in the intervention group this was 0.14, p= 0.947 with the difference between the 2 groups not being statistically significant (p= 0.620). However, the percentage change in Albumin in the placebo group was 2.76, p= 0.185 and in the intervention group was 9.71, $p \leq 0.001$ with the difference between the 2 groups being statistically significant (p= 0.031)

Change in Vitamin B12, Zinc and Magnesium:

Table 4 demonstrates the change in the outcome of Vit B12, Zinc and Magnesium at 1 month. The placebo group percentage change of Vit B12 was 14.81, p= 0.286 and in the intervention group was 11.98, p= 0.339 with the difference between the 2 groups not being statistically significant (p= 0.384). For magnesium, the placebo group percentage change was 2.5, p= 0.121 and in the intervention group the percentage change was 2.5, p= 0.153 with the difference between the 2 groups not being statistically significant (p= 0.942). For zinc, the percentage change in the placebo group was 4.20, p=0.083 and for the intervention group this was 2.4, p= 0.020 with the difference between the 2 groups not being statistically significant (p= 0.634)

Linear regression model:

To ensure that the above effects are not due to confounders, a linear regression analysis was performed to test the effect of the intervention on changes in main study variables. Table 4 demonstrate the association between weight, muscle mass %, fat mass %, Albumin and total protein change in the intervention compared with the placebo, adjusted for age and gender. Those in the intervention group had a mean difference of 2.11 kg of weight loss compared with the placebo with this results being statistically significant [95% CI (-3.52, -0.70), P = 0.004]. Both muscle and fat mass % showed similar outcome to the paired t-test with percentage gain in muscle mass and percentage loss in fat mass, however, similar to the t-test, results were not statistically significant [2.96 (-1.55, 7.48), p = 0.19 for muscle mass % and -2.23 (-5.39, 0.94), p = 0.16 for fat mass %]. The model for Albumin showed statistically significant association between change in albumin level, even after adjusting for age and gender [7.38 (1.41, 13.34), p = 0.017]. Change in total protein showed no statically significant association with the intervention.

Compliance analysis:

Table a demonstrates the level of compliance across the 2 study groups. 100% of the intervention group consumed at least 80% of their allocated 30 day treatment. However, 86% of the control group (18 patients) consumed the minimum required amount of 80% of their designated zero protein supplement.

Table 1. Demographics and characteristics of study participants at baseline.

	Group A: placebo (n = 21)		Group B: Intervention (n = 21)		P
	Mean	SD	Mean	SD	
AGE	35.2	9.6	33.0	12.9	0.528
Gender, n (%)					1.0
Male	6	(28.6)	6	(28.6)	
Female	15	(71.4)	15	(71.4)	
HT	162.2	9.4	162.7	7.8	0.859
WEIGHT	109.6	19.3	120.7	20.1	0.074
BMI	41.5	5.1	45.7	6.7	0.027
Muscle Mass %	49.6	8.4	45.4	8.4	0.111
Fat Mass %	48.4	7.0	51.7	8.7	0.177
HB	13.0	2.0	12.6	1.5	0.434
TOTAL_PROTEIN	68.3	5.1	70.0	5.0	0.278
ALBUMIN	36.2	3.2	34.0	4.3	0.078
VITAMINB12	270.8	151.4	275.4	120.4	0.913
MAGNESIUM	.8	.1	.8	.1	0.219
ZINC	11.9	1.2	12.1	.7	0.552

Table 2. Change in weight, BMI, fat and muscle mass % from baseline to 1 month follow up.

	GROUP A: placebo (n =21)						GROUP B: intervention (n =21)						
	Baseline		1 Month		Difference	P value	Baseline		1 Month		Difference	P value	P value
	M	(SD)	M	(SD)	(%)	(within group)			M	(SD)	(%)	(within group)	(between group)
WEIGHT	109.	19.3	100	18.	-9.60	<0.00	120.	20.1	107.	19.	-10.69	<0.001	0.003 [b]
BMI	41.5	5.1	37.	4.8	-9.50	<0.00	45.7	6.7	40.6	6.7	-11.16	<0.001	<0.001 [b]
Muscle Mass %	49.6	8.4	50.1	12.	0.50	0.676	45.4	8.4	47.7	12.	2.31	<0.001	0.149 [b]
Fate Mass %	48.4	7.0	46.8	6.5	-1.6	0.008	51.7	8.7	49.1	8.9	-2.62	<0.001	0.153 [b]

[a] paired sample *t*-test (change within the same group) .
[b] independent sample *t*-test (change between the 2 groups).
(-ve values indicate loss at 1 month follow-up while +ve values indicate gain)

Table 3. Change in total protein and albumin % between baseline and 1 month follow up.

	GROUP A: placebo (n =21)						GROUP B: intervention (n =21)						
	Baseline		1 Month		Difference	P value	Baseline		1 Month		Difference	P value	P value
	M	(SD)	M	(SD)	(%)	(within group)			M	(SD)	(%)	(within group)	(between group)
TOTAL_PROTE	68.	5.1	68.	4.1	0.88	0.597	70.0	5.0	70.	4.9	0.14	0.947	0.620 [b]
ALBUMIN	36.	3.2	37.	3.5	2.76	0.185	34.0	4.3	37.	3.5	9.71	0.000	0.031 [b]

[a] paired sample *t*-test (change within the same group).
[b] independent sample *t*-test (change between the 2 groups) .

Table 4. Change in vit B12, Magnesium and Zinc % between baseline and 1 month follow up.

	GROUP A: placebo (n =21)						GROUP B: intervention (n =21)						
	Baseline		1 Month		Difference	P value	Baseline		1 Month		Difference	P value	P value
	M	(SD)	M	(SD)	(%)	(within group)			M	(SD)	(%)	(within group)	(between group)
HB	13.	2.0	12.	1.7	-3.08	0.123	12.6	1.5	13.	1.2	3.97	0.005	0.002 [b]
VITAMINB12	27	151.	31	177	14.81	0.286	275.	120.	30	225.	11.98	0.339	0.384 [b]
MAGNESIUM	0.8	0.1	0.7	0.0	-2.50	0.121	0.8	0.1	0.8	0.07	2.50	0.153	0.942 [b]
ZINC	11.	1.2	12.	1.6	4.20	0.083	12.1	.7	12.	0.55	2.48	0.020	0.634 [b]

[a] paired sample *t*-test (change within the same group).
[b] independent sample *t*-test (change between the 2 groups) .
(-ve values indicate loss at 1 month follow-up while +ve values indicate gain)

Table 5. Linear regression model representing the change from baseline to 1 month follow up.

Δ variables over 1 month	Mean difference	95% CI	P value*
Weight (kg)	-2.11	(-3.52, -0.70)	0.004
Muscle mass %	2.96	(-1.55, 7.48)	0.19
Fat mass %	-2.23	(-5.39, 0.940	0.16
Albumin	7.38	(1.41, 13.34)	0.017
Total protein	-0.47	(-4.05, 3.11)	0.79

*model adjusted for age and gender

Table a. Compliance data of the groups

Compliance / Group	Number of intervention patient (high protein supplement)	Number of control patients (zero protein supplement)
Consumption of more than 80% of supplement (24 – 30 bottle)	21	18
Consumption of more 50 - 80% of supplement (15 – 24 bottle)	0	3
Consumption of 20 - 50 % of supplement (6 - 15 bottle)	0	0
Consumption of less than 20 % of supplement (6 – 1 bottle)	0	0

All 1-month follow up individual parameters including the changes between baseline and follow up are shown below (Figures 4.a, 4.b, 4.c, ….).

Comparison of individual characteristics and demographics between the 2 groups at baseline:

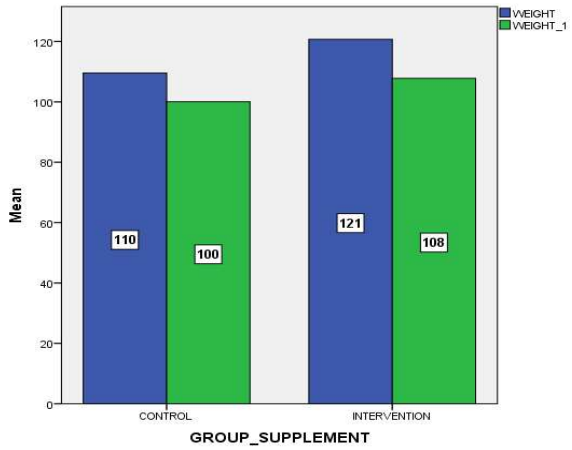


Figure 4.a. Comparison of change in weight between study groups at 1 month

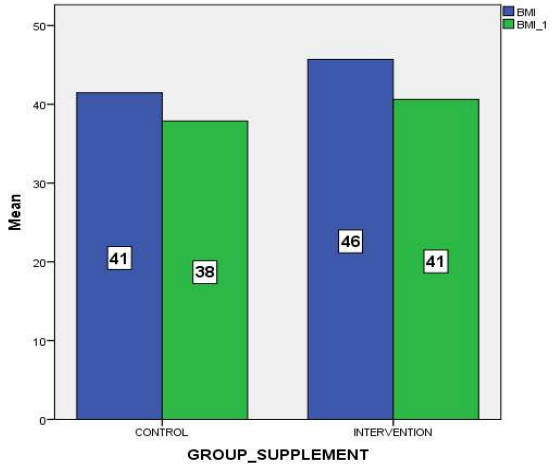


Figure 4.b. Comparison of change in BMI between study groups at 1 month

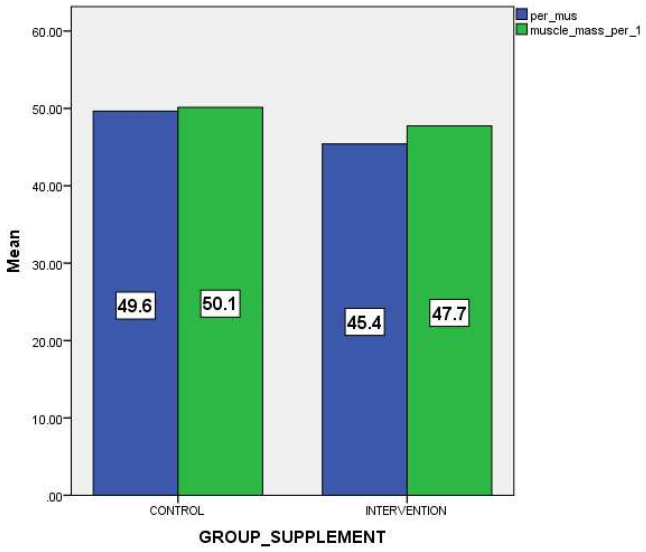


Figure 4.c. Comparison of change in muscle percentage between study groups at 1 month

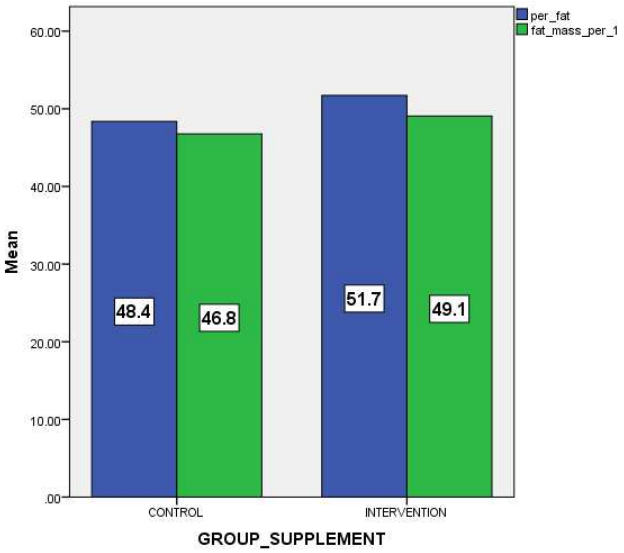


Figure 4.d. Comparison of change in fat % between study groups at 1 month

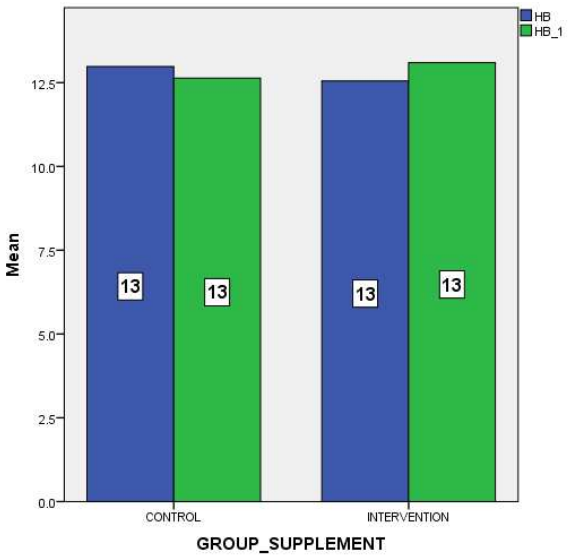


Figure 4.e. Comparison of change in hemoglobin between study groups at 1 month

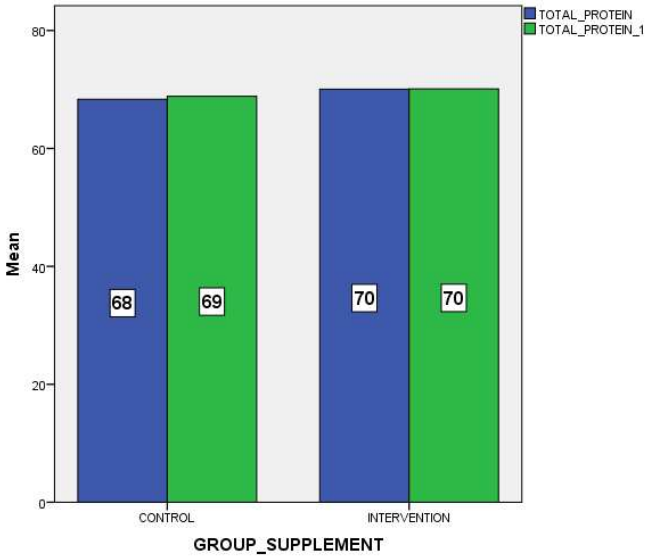


Figure 4.f. Comparison of change in total protein between study groups at baseline

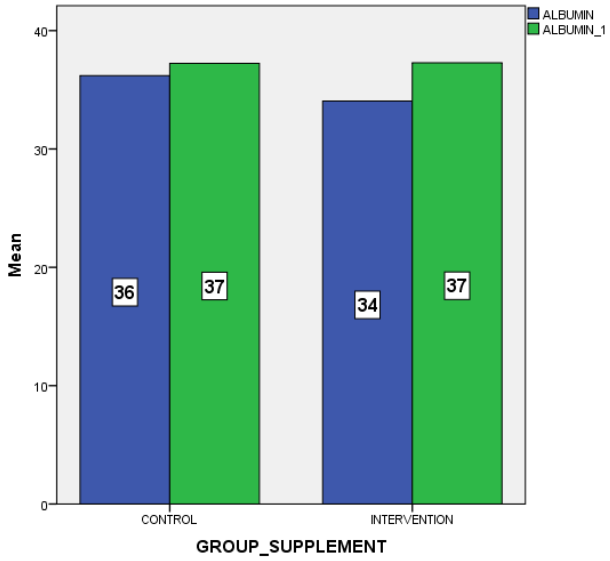


Figure 4.g. Comparison of change in albumin between study groups at 1 month

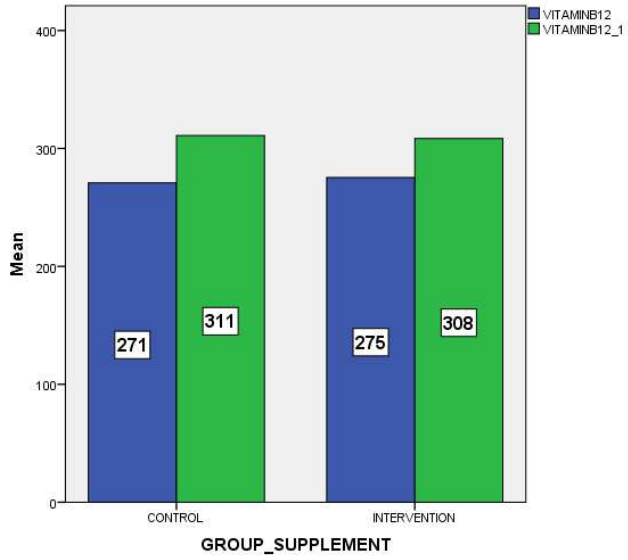


Figure 4.h. Comparison of change in vit B12 between study groups at 1 month

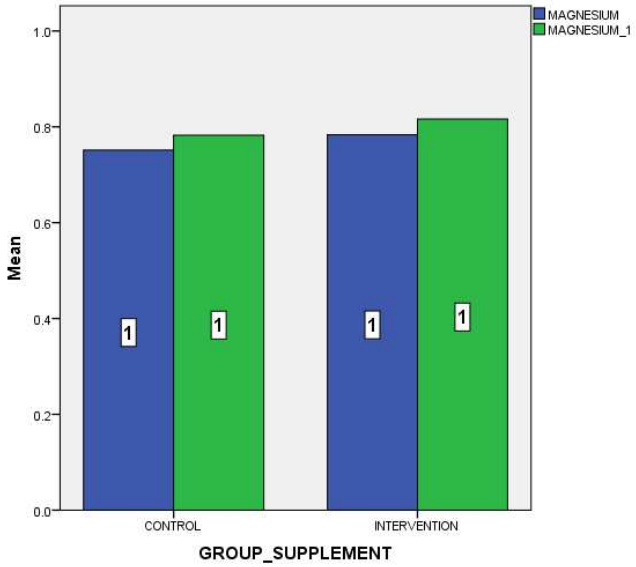


Figure 4.i. Comparison of change in magnesium between study groups at 1 month

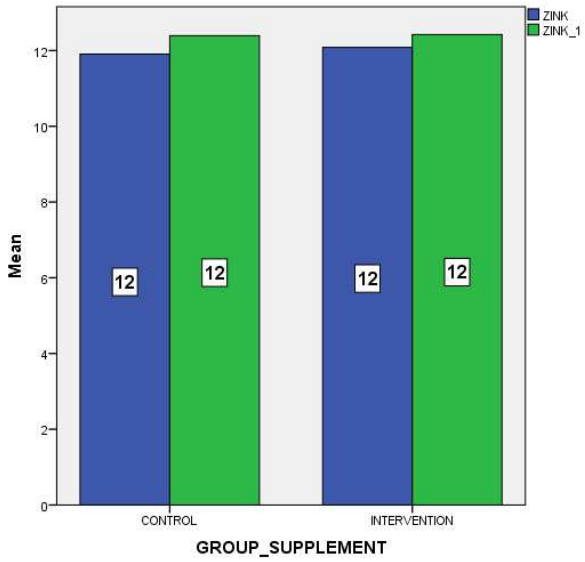


Figure 4.j. Comparison of change in zinc between study groups at 1 month

12. DISCUSSION

The primary objective of this study was to determine the effect of protein supplementation, as a meal replacement, on reducing the risk of developing protein malnutrition that lead to low muscle mass and low protein level. The secondary objectives of our study were to measure percentage change of muscle mass, fat mass, total protein, albumin, Vit B12, Zinc and magnesium levels at 1 month follow up.

Baseline findings:

To assess whether observed differences are real and genuine and to ensure successful randomization, baseline data of study participants were systematically compared between the placebo and the treatment groups. No statistically significant differences were found between the 2 study groups in relation to any of the above parameters, except forthe BMI. The above results confirm the lack of selection bias that, if present, may influence the results of the trial.

The CONSORT statement for Randomized clinical trials recommends that baseline demographics and clinical characteristics for each group are presented (Altman, 1996).However, the statement also demonstrates that “significance testing of baseline differences in randomized controlled trials (RCTs) should not be performed, because it is an excessive measure and can mislead investigators and their readers” (de Boer et al.,

2015). This study complies with the CONSORT statement in that a simple t-test was conducted to compare the means between placebo and treatment groups to ensure no significant differences at baseline existed between the 2 groups in relation to the studied outcomes. The researchers felt that this step was particularly important for the current sample size, where sampling error may be more likely to take place (probability concept).

Only one statistically significant difference was found between the intervention and the placebo groups out of all baseline characteristics we measured. Body Mass Index (BMI) was found to be statistically significantly different between placebo and treatment groups [(41.5 ± 5.1) for placebo and (45.7 ± 6.7) for the treatment, P value of difference = 0.027)]. These findings may indicate that the treatment group was marginally but significantly heavier than the placebo group. However, while BMI numbers tell us a lot about the health status and particularly about the risk of developing diseases such as heart disease and diabetes in an individual and the population, these numbers are somewhat too crude to be a useful measure in assessing and analyzing changes in body fat and muscles (Casey, 2003). In this study, the impact of protein supplementation on changes of body composition and essential substances was assessed. Recently, research studies have focused on analyzing fat percentages as an indicator and a more useful measure of weight-related diseases than BMI (Gallagher et al., 2000). The most common and essential variables used to assess longitudinal analysis in weight loss interventions are weight percentage, muscle mass and percentage, fat mass and percentage, while albumin

and total protein seem to be the measurements of choice as they provide more accurate analysis of the actual changes in accordance to the objectives of this study. The choice of variables for the longitudinal analysis in this study is consistent with the majority of these recent studies done on weight loss intervention, both surgical and non-surgical (Moldovan et al., 2016; Himbert, Ose, Delphan, Ulrich, 2017). In addition, the maintenance of muscle mass or fat-free mass has been associated with weight loss maintenance (Stiegler & Cunliffe, 2006).

Moreover, the probability of finding one statistically different variable between the randomized groups is probably that "chance" that randomization may encounter and therefore it is not, considered a failure of randomization. In fact, and as mentioned previously, the CONSORT statement cautions researcher against "significant testing" of baseline differences in RCTs and clearly states that this should not be performed.

The target variables were analyzed using Tanita's body composition analyzer. This sophisticated analyzer provides objective measures of body composition including Weight, Body Fat Percentage and Body Fat Mass. A large number of recent trials and weight loss studies have used Tanita's body composition analyzer (Li et al., 2013; Shim et al., 2014). The choice of Tanita is primarily based on the high level of technology the analyzer uses to accurately monitor and assess body composition utilizing the latest advanced *bioelectrical impudence analysis* technology that has been developed over the last 25 years. The technology is particularly accurate in detecting changes in body

composition due to adopting fitness program or undergoing a weight loss intervention (Verney et al., 2015*;* Gába et al., 2015; Beeson et al., 2010;Boneva-Asiova&Boyanov, 2008*).*

One month follow up:

Our study showed that a month after the surgery, there has been an observed difference between the 2 groups in weight loss (kg), BMI, muscle mass percentage change, fat percentage change and Albumin percentage change. All other parameters (Total protein, Vit B12, Magnesium and Zinc) did not show any significant, or even a trend towards significant, difference between the 2 groups.

Protein supplementation was able to induce greater weight loss, muscle mass percentage gain and fat mass percentage loss than the dietary advice alone, only a month after the bariatric surgery done on all participants. Although only the weight loss results were statistically significant (mean weight loss of 10.69kg, p= 0.003), both muscle mass % gain and fat mass % loss showed trends towards statistical significance (12.78%, p= 0.149 and -7.74%, p= 0.153, respectively). Our findings are consistent with studies that investigated the impact of protein supplementations, and those that looked at the effect of high content protein meal-replacement programs, on changes in body compositions. A number of studies have shown the effectiveness of protein supplementation on the reduction of weight in post-bariatric surgery patients (Moize et al., 2003; Maïmoun et al., 2017; Coen et al., 2015). These studies have clearly supported the notion that when

post-bariatric patients adhere to a high protein diet their objectives of weight loss, for both clinical reasons and image issues, will achieve better results. Bariatric surgery, although an effective intervention, can only be sustainable the combination of healthy lifestyle including healthy eating (de Jong&Hinnen,2017; Herring et al., 2017). These patients need to be reminded that lifestyle factors and behavioral issues might have contributed largely to their excess weight over the years. They need to be reminded that although they have taken drastic measures to reduce weight to a healthy level, this can only be a start and the rest of the journey of weight loss and maintenance can only be done when a strong will is involved to make other changes, including eating habits and exercise.

Our findings in regards to muscle and fat % change from baseline to 1 month follow-up, although not statically significant, are also consistent with a number of studies. When we look closely at these results we find that the intervention group muscle % (12.78) is healthier than that of the placebo group % (1.59), with a p value of the difference being 0.149,these results show trend towards significance. We think that these are positive findings given the trial period of 1 month and the sample size of our RCT. Perhaps with a longer period of follow up and a larger sample size the difference in muscle mass % between the intervention and the placebo groups could have been larger and more statistically significant. While these can be looked at as researchers or investigators conventions, there has been world-class reports that justified this point when

trials with short follow up were extended to longer follow up time the results were statistically significant or at least highly improved (Weerasooriya, 2011).

Similar results to muscle mass % change were found for fat mass % change. Our study showed that after 1 month follow-up the change in fat % was +3.4 in the placebo group and -7.74 in the intervention group with a p value of 0.153. Once more, while the p value does not reflect statistical significance, we believe these are positive results from the perspectives of our study objectives. The intervention group have lost 7.74 % of their body fat while the placebo group, although they have lost fat in the form of total weight loss, their body fat % change has increased by 3.4%. The results in both groups can be partially explained by the loss and gain of muscle mass % which could have naturally affected the fat %. This is a great result, and similarly to our explanation of the statistical significance of the muscle mass % change, a longer follow-up period and a larger sample could have possibly pushed the p value of 0.153 to a more statistically significant value (i.e. ≤ 0.05).

Studies looking at the effect of protein supplementation or protein rich diet in post-bariatric surgery patients have been consistent with our findings on the change in fat and muscle mass % (Moize et al., 2003; Bohl et al., 2015). Some of these studies with longer follow-up time than our trial have managed to show statistically significant results (Moldovan et al., 2016). However, there have been studies that also showed the lack of effect of protein rich diet or supplementations on changes in fat and muscle mass % (van

den Broek, 2016).

Our study also found that albumin serum level but not total protein was enhanced by the protein supplementation. Our findings showed that the placebo group after 1 month of follow-up gained 2.76% of albumin while the intervention group gained 9.71% of albumin over the same period with a p value of the difference of 0.031. These are definitely interesting, and at the same token, encouraging results, that the protein supplementation has had positive influence on albumin gain and maintenance but not the total protein. This is consistent with the science of muscle growth that mainly requires albumin (Visser et al., 2005).Our findings at the protein level and specifically albumin are consistent with other studies in this field (Schollenberger et al., 2016). The above study showed that protein supplementation after bariatric surgery improves body composition by enhancing loss of body fat mass and reducing loss of lean body mass within the 6 months follow up.

We found no significant effect of the 1 month protein supplementation on the levels of Vit B12, Magnesium or Zinc. These results could be due to the short period of the trial. Perhaps these micronutrients can only start to show effect after a period of time. Studies on the effect of protein supplementations on the concentration of the above micronutrients and vitamins have shown conflicted results. In some studies they found that high rate of nutritional deficiencies is common after bariatric surgery with low

adherence to the nutritional supplementation regimen (Ben-Porat et al., 2017). Other study performed a prospective nutritional status evaluation before and at 2 and 5 years after SG in morbid obese patients receiving multivitamin and mineral supplementation found that about half of patients show some micronutrient deficiency at medium long term, despite supplementation (Pellitero et al., 2017; Mahawar, 2017; Alvarez-Leite, 2004).

As we mentioned earlier in this thesis, protein supplementation has been recently by HMC as a routine procedure for post-bariatric surgery patients. Our RCT is the first in Qatar to use scientific evidence to show the beneficial effect of protein supplementations on Qatari obese patients post bariatric surgery through a scientifically balanced assessment backed by a robust design of double-blinded randomized controlled trials that is considered top of the list of the hierarchy of scientific and epidemiological evidence. Our findings provide an additional support to the use of these supplements as part of the post-bariatric surgery dietary protocol.

The uniqueness of our study is that we have looked at a distinctive population (Qatari obese patients), where a number of factors differ from subjects within the same category in the United States or other western countries. The environment in Qatar and the culture of Qatar society is influenced by a variety of traditional and context specific dynamics. Therefore, it is essential to show the effect of protein rich diet in post-bariatric patients in this specific setting so findings can apply to the context in Qatar. The primary

objectives of our study were to show the impact of protein supplementation on body composition in obese Qatari patients post bariatric surgery. We have done this through one of the highest level of evidence using a double-blinded randomized controlled trial.

LIMITATION

Our study has a number of limitations. Firstly, the placebo group was given a solution that had 100 calories while the intervention group was given 250 calories. If anything, the intervention group will be disadvantaged by having those extra calories in their supplements. Also, the researchers did not objectively monitor the use of the treatment and therefore compliance may have been an issue here. It was practically impossible to determine the exact amount of protein (or placebo) that the participants have taken over the trial period. However, all attempts were made to follow up participants with phone calls to ensure compliance (data based on these phone calls were recorded and 80% of compliance was determined). The purpose of these phone calls was to ensure compliance in taking the supplements. A further limitation was the lack of information on diet. If participants had different diet regimen, then it is likely that this may have affected the results. However, it is well known that bariatric surgery patients generally adhere to liquid diet provided by the healthcare provider (or a dietitian) and it is almost impossible for them at this early stage to ingest any solid foods outside the easily digestible and recommended.

Another limitation is the fact that we included participants who have undergone 2 types of bariatric surgery. This may have potentially affected the outcome. However,a recent study done on approximately 1000 post-bariatric patients has shown that no significant differences have been noted in weight loss and other parameters following different types of bariatric surgeries before one year (Pham et al., 2014).

13. CONCLUSION

Obesity continues to be a major risk factor for a large slice of the population and for the majority of lifestyle NCDs. This highlights the importance of weight loss treatments and intervention, both surgical and non-surgical. High protein diet post-bariatric surgery is a simple non-invasive intervention. Our study has confirmed findings from other recent studies that protein supplementation in post-bariatric surgery patients, who finds it extremely unpleasant to digest normal foods, is an effective intervention to improve weight loss. We have also found after 1 month of follow up that patients who took the treatment displayed higher level of serum albumin than those who took dietary advice alone. We have also shown trends towards significance in results of muscle and fat % change between the 2 groups. Our findings confirm previous research findings that meal replacement and liquid high protein diets can possibly put an end to "food craving" which is a process involved in crafting obesity in the first place. If food craving is not controlled, surgery alone cannot possibly provide a magical solution to obese individuals. This is very important and it must be well communicated with patients prior and following bariatric surgery. Patient education nowadays is a large part of treatment and prevention and healthcare providers, in this instance, must be more committed than ever to informing their patients of how they are expected to behave to ensure sustainability of weight loss.

14. RECOMMENDATIONS

While surgery to reduce weight should be only performed in situations where the tertiary care needs are absolutely met for severely obese patients, we can say, based on our randomized clinical trial that bariatric surgery in combination with protein supplementation seems to be an effective method of weight reduction without loss of protein and muscle mass. It is also effective in reducing total fat %, which has been linked to a number of non-communicable diseases (as mentioned in our literature review). Our research suggests that bariatric surgery should be associated with high protein diet where all efforts are made to ensure compliance for optimal outcomes. This should be clearly explained to patients prior and post-surgery and patients should be convinced that the effectiveness of the surgical intervention may rely on this. We also recommend that adherence to high protein diet (fluid at early stages) is to be part of patient education in post-bariatric surgery care. The effectiveness of this can be accessed via means of follow-ups that include various methods of testing. After all, these approaches are designed to help patients achieve their goals in reducing their weight and keeping it off. We also recommend rather strongly that although bariatric surgery combined with high protein diet is an effective solution to obesity, healthy lifestyle and behavior stay the most crucial factor in living healthy and keeping the weight off. Healthy eating and exercise not only help reduce weight and keep it off, they are also

essential factors in cardiovascular health, mental health and many other health improvements. We recommend that once the body weight of post-bariatric patients has reached a moderate level (i.e. overweight replacing obese or morbidly obese), patients need to enroll in regular physical activity and upgrade their eating habits to healthier alternatives.

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16. Appendices

Appendix A. Informed Consent

نموذج الموافقة على الاشتراك ببحث علمي
RESEARCH CONSENT FORM

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH · EDUCATION · RESEARCH صحة · تعليم · بحوث

1. Title of research	1. عنوان البحث
Protein supplementation impact on body muscle mass and fat mass in Qataris post bariatric surgery, Randomized Controlled Trials (RCTs)	تأثير المكمّلات البروتينية على الكتلة العضلية و الدهنية لدى القطريين بعد جراحة علاج السمنة: دراسة بحثية منضبطة عشوائية
2. Principal Investigator	**2. الباحث الرئيسي**
Sahar Al Shammari, Hamad Medical Corporation	سحر الشمري، مؤسسة حمد الطبية
3. Why are we inviting you to join this research?	**3. لماذا ندعوك للإنضمام إلى هذا البحث؟**
The investigator and colleagues at Hamad Medical Corporation (HMC) – Bariatric department are conducting this research. We are inviting you to join because you are Qatari patient with age between 18-45 years who has undergone a bariatric surgery recently at HMC.	الباحث وزملائه في مؤسسة حمد الطبية – قسم جراحات السمنة يدرون اجراء هذا البحث. أنت مدعو/ة للمشاركة لأنك مريض قطري في الفئة العمرية بين 18-45 سنة وقد أجريت عملية لعلاج السمنة مؤخرا بمؤسسة حمد الطبية.
4. What should you know about this research?	**4. ما الذي يجب أن تعرفه عن هذا البحث؟**
• We will explain the research to you • Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate) • Please feel free to ask questions or mention concerns before deciding, or during or after the research • You can say yes but change your mind later • We will not hold your decision against you	• سنقوم بشرح البحث لك بشكل وافٍ • قرار انضمامك للمشاركة بهذا البحث أو عدمه يعود لك (يمكنك قبول أو رفض المشاركة بغض النظر عن من يدعوك للمشاركة) • لك مطلق الحرية بأن تسأل أي سؤال قبل اتخاذ قرارك, أو خلال أو بعد المشاركة بالبحث. • إذا وافقت على المشاركة, بإمكانك أن تغير رأيك لاحقاً لن يستخدم قرارك ضدك بأي حال من الأحوال
5. Who can you talk to?	**5. مع من يمكنك التحدث؟**
If you have questions or concerns, or if you think the research has hurt you, talk to the research team at: Ms. Sahar AL Shammari 70995505 - 44396792 If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact: • HMC Medical Research Centre at irb@hamad.qa	لطرح أية أسئلة أو مناقشة أي مخاوف, أو إذا كنت تعتقد أن البحث قد أضر/يضر بك, قم بالتحدث مع فريق البحث على: 44396792 – 70995505 إذا كان لديك أسئلة حول حقوقك كمشارك بالبحث، أو كنت ترغب في التحدث مع شخص من خارج فريق البحث، يرجى الإتصال ب: • مركز الأبحاث, مؤسسة حمد الطبية, إيميل: irb@hamad.qa
6. Why are we doing the research?	**6. لماذا نقوم بهذا البحث؟**

This study is to see the impact of the intervention in post bariatric patient in many sides like weight reduction and improvement of nutritional status in general. We would like to assess the effect of protein supplementation on changes in health parameters in Qatari patients post bariatric surgery. We will be assessing these changes by measuring few parameters like muscle and fat mass, body weight, proteins, Vit B12 and minerals like Magnesium and Zinc.	هذه الدراسة لمعرفة تأثير التدخل النوعي في مرضى بعد عملية علاج السمنة من عدة نواحي تشمل إنقاص الوزن و تحسين التغذية بشكل عام. نريد تقييم تأثير المكمّلات البروتينية على صحة المرضى القطريين بعد عملية علاج السمنة. سنقوم بتقييم هذه التغييرات عبر قياس بعض المؤشرات الحيوية مثل الكتلة العضلية و الدهنية، الوزن، فيتامين ب-12 و المعادن مثل المغنيسيوم و الزنك.
7. How long will the research take?	**7. كم من الوقت سيستغرق هذا البحث؟**
We think that you will be in the research for 3 months starting from the first day post-operative. We expect the research to last for 6 months.	نعتقد أنك ستكون في البحث لمدة 3 شهور من أول يوم بعد العملية. نتوقع أن يستمر البحث لمدة 6 شهور.
8. How many people will take part?	**8. كم عدد الأشخاص الذين سيشاركون بهذا البحث؟**
We plan to study 80 people (post bariatric patients) from HMC. They will be divided in 2 groups equally.	نحن نخطط لدراسة 80 شخص (مرضى عمليات علاج السمنة) من مؤسسة حمد الطبية. سيتم تقسيمهم الى مجموعتين بالتساوي.
9. What happens if you take part?	**9. ما الذى سيحدث اذا قررت الاشتراك بهذا البحث؟**
If you agree to take part, you will be "randomized" into one of 2 study groups - One will be intervention group and one would be the control group. This trial will be a double-blinded study. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a 50% chance of being place in a specific group. Neither you nor the researchers choose which group you will be in. As a part of the standard care for post bariatric patients, all patients will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies. If you are from Intervention group: 1. You will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies. 2. Before discharge from the hospital, you will have a store request for supplement and will be advised by the dietitian regarding its use (one can per day, over 3-5 intervals).	اذا وافقت على المشاركة، سوف يتم "اختيارك عشوائياً "في واحدة من مجموعات الدراسة – مجموعة التدخل و المجموعة الثانية للمقارنة. التوزيع العشوائي يعني أن إلحاقك بأي مجموعة من مجموعات البحث سيتم عن طريق الصدفة. مثلاً برمي العملة النقدية أو القرعة. لا أنت ولا الباحثين ستتمكنون من اختيار المجموعة التي سوف تكون فيه. كجزء من الرعاية القياسية للمرضى بعد عمليات علاج السمنة، يحصل جميع المرضى على استشارات للتغذية عبر أخصائي التغذية أثناء الجولة الروتينية و ذلك لإرشادهم للتغذية السليمة بعد العمليات و تجنب مضاعفات بسبب نقص التغذية. اذا كنت في مجموعة التدخل: 1) ستحصل على إستشارات غذائية عن طريق أخصائي التغذية أثناء الجولة الروتينية و ذلك لإرشادهم للتغذية السليمة بعد العمليات و تجنب مضاعفات بسبب نقص التغذية. 2) ستستلم طلب موجه للمخزن لإستلام مكمّل غذائي بتركيز عالي للبروتين و بعض الإرشادات من أخصائي التغذية عن كيفية استعماله (عبوة واحدة يوميا على 3-5 فترات) 3) و تحتوي العبوة الواحدة للمكمّل (200 ملل) على 20 جرام بروتين، 250 كيلو كالوري و بعض العناصر الغذائية المهمة. 4) عند إستلام المكمّلات من مخزن المستشفى، سيقومون بتزويدك ببعض المعلومات الاضافية لضمان الاستخدام حسب متطلبات الدراسة.

3. Supplement contains (per 200 ml can) 20 g of protein, 250Kacl plus different micronutrient and macronutrient (Cubitan Protein, Nutricia, Netherlands).
4. When you collect your supplement package from the hospital store, they will provide you with instructions about the use the supplement to ensure protocol is followed.

If you are in the control group:
1. You will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies.
2. Before discharge from the hospital, you will have a store request for supplement and will be advised by the dietitian regarding its use (one can per day over 3-5 intervals).
3. Following hospital discharge, you will receive supplement contains per can (200 ml), 0g protein, fat free, 100 kcal and enriched with electrolytes (preOp, Nutricia, Netherlands).
4. When you collect your supplement package from the hospital store, they will provide you with instructions about the use the supplement to ensure protocol is followed.

Measurements for both groups:

- Baseline measurement of body composition (fat mass and muscle mass), height and weight will be conducted on day one of the trial.
- Baseline blood test for total protein, albumin, Vit B12, Zink and Magnesium levels.
- All of the above measurements will be repeated at 1 and 3 month after surgery. Collection of blood samples at 1 & 3 months post the surgery is part of routine practice for post-bariatric surgery patients.

Study visits for both groups:

<u>One and 3 months after surgery (1 day each visit)</u>

a) Post-surgery dietary advice, to sustain a hypo caloric and protein-rich diet.
b) Anthropometric parameters for body composition (fat and muscle mass will be measured to assess healthy weight).
c) Give blood sample after an overnight fasting. All blood markers will be measured and calculated in the central laboratory in HGH.
d) Both groups will be asked about their supplement compliance to determine their eligibility to continue in study.
e) All randomized patients will be analyzed by intention to treat (ITT) analysis

إذا كنت في مجموعة المقارنة:
1) ستحصل على إستشارات غذائية عن طريق أخصائي التغذية أثناء الجولة الروتينية و ذلك لإرشادهم للتغذية السليمة بعد العمليات و تجنب مضاعفات بسبب نقص التغذية.
2) ستستلم طلب موجه للمخزن لإستلام مكمّل غذائي وبعض الإرشادات من أخصائي التغذية عن كيفية استعماله (عبوة واحدة يوميا على 3-5 فترات)
3) و تحتوي العبوة الواحدة للمكمّل (200 ملل) على20 جرام بروتين، خالي الدهون، 100 كيلو كالوري و بعض العناصر الغذائية المهمة.
4) عند إستلام المكمّلات من مخزن المستشفى، سيقومون بتزويدك ببعض المعلومات الاضافية لضمان الاستخدام حسب متطلبات الدراسة.

القياسات للمجموعتين:

- قياسات أولية لكتلة الجسم (العضلات و الدهون)، الوزن، الطول في اليوم الأول للدراسة
- تحليل دم أول لقياس مستوى البروتين، الزلال، فيتامين ب12، الزنك و المغنيسيوم.
- سيتم اعادة القياسات السابق ذكرها بعد شهر و 3 شهور عند نهاية المشاركة في الدراسة.

زيارات بحثية للمجموعتين:

<u>بعد شهر من الجراحة</u>

a) نصائح عن التغذية ما بعد العملية للمحافظة على نظام قليل السعرات و غني بالبروتينات.
b) قياسات لمؤشرات كتلة الجسم
c) عينة من الدم بعد صيام ليلة. سيتم عمل التحاليل في مختبرات مستشفى حمد
d) سيتم سؤال المشاركين في المجموعتين عن التزامهم بالمكمّلات لتحديد مواصلتهم في البحث
e) جميع المرضى الذين تم توزيعهم عشوائيا سيتم تحليلهم بطريقة "الية للعلاج" الخاصة. (ITT Analysis)

10. Could the research be bad for you?	**10. هل يمكن لهذا البحث أن يضرك؟**
The research does not pose any risk to the participants in the intervention and control group. The intervention doesn't have any side effect for any of the 2 groups. You will not be included in the study if you have: 1) Any Renal or liver disease because that will affect protein or albumin level in body. 2) Past history of bariatric surgery 3) Baseline tests showing you are in need for protein supplements. In this case, you will be given the needed protein supplements per the standard care. 4) You are not willing to participate.	الاجراءات المتعلقة بهذا البحث لا تشكل خطراً على المشاركين في المجموعتين. لا توجد أي آثار جانبية للمكمّلات البروتينية. لن تستطيع المشاركة في هذه الدراسة اذا كانت لديك: 1) أمراض في الكلى أو الكبد و التي من شأنها التأثير على مستوى البروتين أو الزلال في الجسم 2) سجل تاريخي بعمليات السمنة 3) حاجة للمكمّلات البروتينية حسب الفحوصات الأولية. في هذه الحالة سيتم اعطائك هذه المكمّلات كجزء من الرعاية العادية لهذه الحالات.
11. Could the research be good for you?	**11. هل يمكن لهذا البحث أن يفيدك؟**
There are no benefits to you from joining this research. However, possible benefits to others include the importance of intervention to their health status and weight reduction. If the protein intervention proves to be beneficial, we will recommend this to the respective authorities for implementation.	لا توجد فوائد من انضمامكم لهذا البحث. ومع ذلك، فالفوائد المحتملة للآخرين تشمل معرفة جدوى التدخل النوعي لتحسين حالتهم الصحية و إنقاص الوزن. إذا ثبت وجود فوائد مباشرة للمكمّلات البروتينية، سنقوم برفع توصيات للجهات المختصة لتطبيقها.
12. What happens to information about you?	**12. ما الذي سيحدث للمعلومات عنك؟**
We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research. We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include: • Members of the research team whose work is related to the research or to protecting your rights and safety • Representatives of the Ministry of Public Health who make sure the study is done properly and that your rights and safety are protected • Your doctors and nurses	سنحرص على حماية المعلومات المتعلقة بك. وهذا سيتضمن استخدام رمز للتعرف عليك في سجلاتنا بدلاً من استخدام اسمك. ونحن لن نحدد هويتك الشخصية في أي تقارير أو مطبوعات ناتجة من هذا البحث. لا يمكننا ضمان السرية التامة، ولكننا سنحدّ من إمكانية الوصول إلى المعلومات المتعلقة بك وعنك. فقط الأشخاص الذين سيكونون بحاجة لمراجعة معلوماتك سيتمكنون من الوصول إليها. هؤلاء الأشخاص ممكن أن يكونوا: • فريق البحث المرتبطة أعمالهم بهذا البحث او بحماية حقوقك وسلامتك • ممثلي وزارة الصحة العامة في قطر التي تتأكد من قيام الدراسة بالشكل الصحيح وتتأكد من حماية حقوقك وسلامتك. • أطباؤك وطاقم التمريض
13. What if you don't want to join?	**13. ماذا لو كنت لا تريد المشاركة؟**

You can say no and we will not hold it against you.	يمكن ان ترفض المشاركه في البحث ولن يستخدم قرارك ضدك بأي حال من الأحوال.
14. What if you join but change your mind?	**14. ماذا لو انضممت الآن ولكن غيرت رأيك لاحقاً؟**
You can stop participating at any time and we will not hold it against you. You may inform the research team through the available contact information and we will exclude the data we collected about you from this study.	يمكنك التوقف عن المشاركة بهذا البحث بأي وقت، ولن يستخدم قرارك ضدك بأي حال من الأحوال إذا توقفت عن المشاركة بالبحث، يرجى الاتصال بنا لحذف المعلومات التي جمعناها عنك مسبقاً.
15. What else should you know?	**15. .ما الذي يجب أن تعلمه أيضاً؟**
The research is approved by the Medical Research Center – HMC. The researcher might stop this study at any time or decide to stop your participation in this study even if you want to continue. This could happen for the following reasons: • If you did not take at least 80% of their intervention product amount per day, or • If you did not take the intervention product (supplement) for more than 3 days per week.	تمت الموافقة على هذا البحث من مركز البحوث الطبية بمؤسسة حمد. قد يقوم الباحث أو راعي البحث/موله بوقف الدراسة أو انهاء مشاركتك في الدراسة في أي وقت، حتى لو كنت تريد الاستمرار .وهذا يمكن أن يحدث للاسباب التالية: • عدم الالتزام بالمكملات بنسبة 80% على الاقل للجرعة اليومية • عدم الالتزام بالمكملات لأكثر من 3 أيام في الاسبوع

نموذج الموافقة على الاشتراك ببحث علمي
RESEARCH CONSENT FORM

Signature Page for Capable Adult	صفحة التوقيع للمشارك البالغ العاقل
Volunteer	**المشارك**
I voluntarily agree to join the research described in this form.	أوافق طوعاً على الانضمام الى البحث المشروح في هذا النموذج
Printed Name of Volunteer	الاسم الكامل للمشارك بالبحث
Signature of Volunteer Date	التوقيع التاريخ
Person Obtaining Consent	**الشخص الحاصل على الموافقة**
I document that: • *I (or another member of the research team) have fully explained this research to the volunteer.* • *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*	أشهد أني: • أنا (أو أحد أعضاء فريق البحث) قمنا بشرح البحث بشكل وافي للمشارك بالبحث • قمت شخصياً بتقييم فهم المشارك بالبحث والحصول على موافقته/ها الطوعية.
Printed Name of Person Obtaining Consent	الاسم الكامل الشخص الحاصل على الموافقة
Signature of Person Obtaining Consent Date	التوقيع التاريخ
Witness (if applicable)	**الشاهد (عند الضرورة)**
I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.	أشهد أنه تم شرح المعلومات الواردة في هذا النموذج بدقة (وأية معلومات أخرى مكتوبة) للمشارك بالبحث. إنه يبدو أنه قد فهم البحث وأن موافقته على الإنضمام إلى هذا البحث طوعية.
Printed Name of Witness	الاسم الكامل للشاهد
Signature of Witness Date	التوقيع التاريخ

Appendix B. Institutional Approval (IRB)

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH - EDUCATION - RESEARCH صحة - تعليم - بحوث

مركز البحوث الطبية
Medical Research Center

Ref. No: MRC/0473/2017
Date: 8th March 2017

Ms. Sahar Dahawi Alshamari
Senior Clinical Dietitian
Dietetics & Nutrition
Surgery
HGH

Dear Ms. Sahar,

Subject: Research Proposal 16433/16 "Protein Supplementation Impact on Body Muscle Mass and Fat Mass in Qataris Post Bariatric Surgery, Randomized Controlled Trails (RCTs)"

The above titled Research Proposal submitted to the Medical Research Center has been approved to be conducted in HMC provided that the continuing approval from the HMC Institutional Review Board (IRB) is renewed as per the committee terms. The Research Center has acknowledged the IRB approval (Full Board) letter dated 16th February 2017.

This research study should be conducted in full accordance with all the applicable sections of the Rules and Regulations for Research at HMC and you should notify the Medical Research Center immediately of any proposed changes in study conduct that may affect the resource utilization at HMC. It is the Principal Investigator's responsibility to obtain review and continued approval if there is any modification to the approved protocol.

A study progress report should be submitted annually and a final report upon study's completion.

We wish you all success and await the results in due course.

Yours sincerely,

Prof. Ibrahim Janahi
Executive Director of Research
Medical Research Center

Cc:
1. Study Investigators
2. Chairman of HGH Research Committee

Sa

Tel: (+974)4439 2440
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P.O.Box 3050
Doha, Qatar
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Appendix C. Data Collection Form

Data Collection Form – RCT Study

Personal Information

Study Number	
Gender (Female/ Male)	
Age	
Type of Surgery	

Anthropometrics Data: **HT:**

	Baseline	One Month	3 Months	Total
Date				
Weight				
BMI				
Muscle Mass				
Fat Mass				

Lab Test:

	Baseline	3 Months
Date		
Hb		
Total Protein		
Albumin		
V12		
Magnesium		
Zinc		

Compliance:

Score of compliance	Not Compliant				Compliant
	1	2	3	4	5

	One Month	3 Months
Diet		
Supplement		

Data Collector's Name: _____

Group: _____

HMC-IRB,16433/16,16Feb17-15Feb18

v29Dec2016

Appendix D. Qatar National Bariatric Guidelines

QATAR NATIONAL BARIATRIC GUIDELINES

Introduction:

Obesity is one of the greatest health problems in Qatar. It is associated with a wide spectrum of comorbidities that has significant burden on health sector. Bariatric surgery is the most successful treatment currently in management of obesity. It is widely performed both in public and private sector. It is a very specific and complex surgery and if not performed in the right setup can be harmful to the patient. These guidelines are aimed to minimize the risk of the surgery and are compiled according to current international guidelines.

Approved bariatric procedures:

Types of Bariatric Surgical Procedures		
	Primary	**Revisional**
1	Sleeve Gastrectomy	Gastric band removal
2	Roux-en-Y gastric bypass	Conversion of gastric banding to Roux-en-Y gastric bypass
3	Adjustable gastric banding	Conversion of gastric banding to sleeve gastrectomy
4	Gastric mini bypass	Revisional sleeve gastrectomy
5	Staged restrictive and malabsorptive procedure	Revisional Roux-en-Y gastric bypass
6	Endoscopic intragastric balloon placement	Endoscopic revisional procedure for weight regain
7	Banded Roux-en-Y gastric bypass	Revision of Roux-en-Y gastric bypass
8		Reversal of Roux-en-Y gastric bypass
9		Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass

These can be offered to patients in general with proper patient selection. Surgeons should perform malabsorbtive procedures with caution as they require meticulous follow up and patient compliance.

All other innovative and investigational procedures can only be performed after obtaining IRB approval in public hospital and in private hospital approval should be obtained from Ministry of Health. The patient should also be informed and consented for the procedure as investigational one.

Indications for surgery:

1. Patients with a BMI >40 kg/m2 without coexisting medical problems and for whom bariatric surgery will not be associated with high risk.
2. Patients with a BMI ≥35 kg/m2 and one or more severe obesity-related co-morbidities, including T2DM, hypertension, dyslipidemia, obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of OSA and OHS), nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), pseudo tumor cerebri, gastro esophageal reflux disease (GERD), hiatal hernia, severe urinary incontinence, osteoarthritis, lumbar disc prolapse, infertility or considerably impaired quality of life, Polycystic ovary syndrome, are considered candidates for bariatric procedure.
3. Patients with BMI of 30–34.9 kg/m2 with uncontrolled type 2 diabetes or metabolic syndrome may also be offered a bariatric procedure if approved by bariatric multidisciplinary team decision. BMI 30-35 (Class I obesity) obesity is a well-defined disease that causes or exacerbates multiple other diseases, decreases the duration of life, and decreases the quality of life. Current options of non-surgical treatment for Class I obesity are not generally effective in achieving a substantial and durable weight reduction. For patients with BMI 30-35 who do not achieve substantial and durable weight loss and comorbidity improvement with non-surgical methods, bariatric surgery should be an available option for suitable individuals. Gastric banding, sleeve gastrectomy, and gastric bypass have been shown in randomized, controlled trials to be safe and effective treatment for patients with BMI 30-35 in the short and medium term.

Hospital set up:

The hospital should be equipped with appropriate facility to manage morbidly obese patients appropriately. These include hospital beds which are specific for morbid obese patients, wheel chairs, CT machines, operating tables etc. The hospital should not be operating on patients exceeding its capability.

The surgery privileges:

Surgeons performing bariatric procedures must be qualified to be operating this specific surgery either through a fellowship program or through acquiring enough surgical experience to warrant them privilege in the specific bariatric surgeon by working under supervision of qualified bariatric surgeon. In order to maintain the privilege any surgeon must be doing a minimum of fifty cases per year.

Preoperative work up:

Each patient should be assessed preoperatively with concise history and physical examination. Any medical co morbidities detected should be managed before the surgery. Investigations should include the basic blood work, CBC, U/E and endocrine tests. A method of detecting any hiatal

hernia is warranted before surgery either through an endoscopy or a barium meal. If the patient has history suggestive of biliary disease an ultrasound abdomen is indicated.
Preoperative and or nutritional education of the patient must be completed with scheduled nutritional evaluation with the program registered dietician. Assessment of the patient's ability to maintain compliance with postoperative vitamin supplementation, dietary changes and behavioral modifications will be completed by the registered dietician. Recommendations put forth by the registered dietician can be taken into account by the operative surgeon in assessing the appropriateness of bariatric surgery for each individual patient

Postoperative follow up:

Regular postoperative follow up is mandatory and should include regular visit to OPD with blood tests and provision of vitamin and mineral supplements (every 3 months for 1 year and then every 6 months for second year and afterwards once a year). Recommended postoperative blood tests to be performed at each visit. Routine blood testing includes CBC, HgA1c, chemistry panel, vitamin (D, B1, B6, B12, folic acid) and minerals (iron, zinc, copper, magnesium) levels.

Monitoring and review requirement:

Each hospital should report and maintain a database with respect to the number of bariatric procedures performed on monthly basis and the number of serious complications if any. If the complications are increased above acceptable number internationally the ministry of health should start an investigational committee and appropriate steps should be taken accordingly.

These guidelines are subject to change according to the updates of international guidelines. An annual review as needed of the guidelines will be conducted by a committee of specialized surgeons and appropriate changes will be made.

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Consultant, Bariatric & Metabolic Surgery - HMC
020860
19-5-14

Dr. Davit Sargsyan
Specialist, Bariatric & Metabolic Surgery - HMC
024910

Dr. Moataz Bashah	Dr. Davit Sargsyan	Dr. Mohammed Al Kuwari
HMC- Consultant,	HMC- Specialist,	HMC- A/Consultant,
Bariatric surgery	Bariatric surgery	Bariatric surgery

Appendix E. Cubitan Supplement Description

Cubitan

Description
Cubitan is a Food for Special Medical Purposes for use under medical supervision. Cubitan is a high protein (20g/200ml), high energy (250kcal/200ml), milkshake style nutritional supplement, designed for the dietary management of patients with chronic wounds. Available in a 200ml bottle, in 3 flavours: Vanilla, Strawberry and Chocolate.

Indications
For enteral use only. Cubitan is available in the Republic of Ireland under the General Medical Services (GMS) Scheme, Long Term Illness Scheme and Drugs Payment Scheme (DPS).

Contraindications
Not for intravenous use. Not suitable for infants and children under 3 years of age. Not suitable for patients with galactosaemia.

Precautions
Not suitable for use as a sole source of nutrition. Only to be used as a supplement to the normal diet. Use with caution in children and adolescents aged 3 - 17 years.

Directions for use
Cubitan is ready to drink and best served chilled. Shake well before use.

Storage
Store in a cool, dry place (5 - 25°C). Once opened, Cubitan should be consumed within 4 hours or stored in a refrigerator for up to 24 hours. Discard unused contents thereafter.

Shelf life
9 months. Best before date: see side of bottle.

Ingredients (Vanilla flavour*)
Milk protein concentrate, water, maltodextrin, sucrose, vegetable oils, L-arginine, acidity regulator (citric acid), flavour (vanilla), sodium L-ascorbate, carotenoids (contains soy) (β-carotene, lutein, lycopene), magnesium hydrogen phosphate, emulsfier (soy lecithin), choline chloride, di potassium hydrogen phosphate, DL-α-tocopheryl acetate, tri potassium citrate, magnesium hydroxide, ferrous lactate, potassium chloride, zinc sulphate, potassium hydroxide, sodium selenite, copper gluconate, sodium chloride, manganese sulphate, nicotinamide, retinyl acetate, folic acid, calcium D-pantothenate, pyridoxine hydrochloride, chromium chloride, riboflavin, D-biotin, cholecalciferol, thiamin hydrochloride, sodium molybdate, sodium fluoride, potassium iodide, phytomenadione, cyanocobalamin.

*For all other flavours please see individual packaging.

CUBITAN IS GLUTEN FREE.

Cubitan

Average Contents	Unit	per 100ml	per 100kcal
Energy:	kcal	125	100
	kJ	525	420
Protein:	g	10	8
nitrogen	g	1.2	1.0
NPC:N		56:1	56:1
arginine	g	1.5	1.2
% of total energy	%	30	30
Carbohydrate:	g	11.7	–
polysaccharides	g	6.6	5.3
sugars	g	7.1	5.7
lactose	g	1.7	1.4
% of total energy	%	45	45
Fat:	g	3.5	2.8
saturates	g	0.4	0.35
% of total energy	%	25	25
Dietary fibre*:			
vanilla	g	0	0
Minerals:			
sodium	mg (mmol)	50 (2.2)	40 (1.7)
potassium	mg (mmol)	150 (3.8)	120 (3.1)
chloride	mg (mmol)	80 (2.3)	64 (1.8)
calcium	mg (mmol)	225 (5.6)	180 (4.5)
phosphorus	mg (mmol)	182 (5.9)	146 (4.7)
magnesium	mg (mmol)	42 (1.7)	34 (1.4)
iron	mg	3	2.4
zinc	mg	4.5	3.6
copper	mcg	675	540
manganese	mg	1.3	1.0
fluoride	mg	0.19	0.15
molybdenum	mcg	19	15
selenium	mcg	32	26
chromium	mcg	13	10
iodine	mcg	25	20
Vitamins:			
vitamin A	mcg RE	119	95.2
– carotenoids	mg	0.75	0.6
vitamin D	mcg	1.3	1.0
vitamin E	mg α-TE	19	15
vitamin K	mcg	10	8
thiamin	mg	0.28	0.22
riboflavin	mg	0.63	0.5
niacin	mg NE	3.4	2.7
pantothenic acid	mg	1.0	0.8
vitamin B6	mg	0.65	0.52
folic acid	mcg	100	80
vitamin B12	mcg	0.79	0.63
biotin	mcg	7.5	6
vitamin C	mg	125	100
Others:			
choline	mg	69	55
Water:	g	80	64
osmolarity	mOsm/l	500	500
osmolality	mOsm/kg H_2O	625	625
potential renal solute load	mOsm/l	715	715

*Trace amounts of fibre in Chocolate flavour.

Appendix F. Pre-Op Supplement Description

preOp

Description
preOp is a Food for Special Medical Purposes for use under medical supervision. preOp is a 0.5kcal/ml, clear, non-carbonated, lemon flavoured, iso-osmolar carbohydrate drink. preOp is designed to switch patients from a fasted to a fed state prior to surgery. It has been shown to moderate metabolic responses to surgery, improve well-being, decrease post-operative insulin resistance and attenuate loss of lean body mass. preOp is presented in a 200ml carton.

Indications
For enteral use only. Safe to use up to 2 hours before surgery. For the preoperative dietary management of surgical patients.

Contraindications
Not for intravenous use. Not suitable for infants. Not suitable for use in emergency surgery and patients with delayed gastric emptying.

Precautions
Not suitable as a sole source of nutrition. Use with caution in children and patients with diabetes.

Directions for use
Patients on morning surgical list:
Loading dose: 4 x 200ml the evening before surgery
Final dose: 2 x 200ml in the morning up to 2 hr before anaesthesia

Patients on afternoon surgical list:
Loading dose: 4 x 200ml the morning of surgery
Final dose: 2 x 200ml up to 2 hr before anaesthesia

preOp is ready to drink and is best served chilled. Shake well before use.

Storage
Store in a cool, dry place (5 - 25°C). Once opened, preOp should be consumed within 4 hours or stored in a refrigerator for 24 hours. Discard unused contents thereafter.

Shelf life
15 months. Best before date: see top of carton.

Ingredients
Water, maltodextrin, fructose, tri potassium citrate, tri sodium citrate, acidity regulator (citric acid), flavour (lemon), sweetener (acesulfame K), sweetener (sodium saccharine).

PREOP IS GLUTEN, LACTOSE, FAT, PROTEIN AND FIBRE FREE.

Average Contents	Unit	per 100ml	per 400ml
Energy:	kcal	50	200
	kJ	215	860
Protein:	g		
Carbohydrate:	g	12.6	50.4
polysaccharides	g	10	40
sugars	g	2.1	8.4
lactose	g	<0.025	<0.025
% of total energy	%	100	100
Fat:	g	–	–
Dietary fibre:	g	–	–
Minerals:			
sodium	mg (mmol)	50 (2.2)	200 (8.6)
potassium	mg (mmol)	122 (3.1)	488 (12.2)
chloride	mg (mmol)	6 (0.2)	24 (0.7)
calcium	mg (mmol)	6 (0.2)	24 (0.6)
phosphorus	mg (mmol)	1 (0.0)	4 (0.1)
magnesium	mg (mmol)	1 (0.0)	4 (0.2)
Water:	g	92	368
osmolarity	mOsmol/l	240	240
osmolality	mOsmol/kg H_2O	260	260
potential renal solute load	mOsmol/l	55	55
pH		4.9	4.9

preOp

Appendix G. Post Bariatric Diet

Post Bariatric Surgery Diet

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH · EDUCATION · RESEARCH
صحة · تعليم · بحوث

قسم التغذية العلاجية
Dietetics and Nutrition Department

Post Bariatric Surgery Diet

This surgery gives the stomach a new shape after removing a large part of it (approximately 80%). The stomach becomes smaller so only small amounts of food can be ingested. So a balanced weight reducing diet should be followed to avoid any complication or side effects.

Any diet for post bariatric surgery will include a total change in a patient's food habits. The patient will stay healthy and maintain the goal of surgery by complying with the dietary instructions below:

Dietary plan guidelines:

- This dietary plan consists of multiple stages starting from the first day post surgery:
    - First stage: Clear Fluids
    - Second stage: Full Fluids (Low Fat and Sugar Free)
    - Third stage: Pureed Foods
    - Fourth stage: Soft Foods
    - Fifth stage: Full consistency/ Regular foods

- Shifting from one stage to another depends on patient tolerance and their acceptance of consumed foods.
- Stop eating when you feel full, otherwise you may develop vomiting, discomfort, or other complications.
- Drink 6-8 cups of water (30-60 ml every 15 minutes)
- Always remember that your new tiny stomach can tolerate only limited amount of foods /30-60 ml (2-4 tablespoons).
- When starting solid foods (full consistency), take only a small amount, eat slowly, and chew the food thoroughly.
- Don't use straws for drinking.

Stages of Dietary Plan

Stage (1): Clear fluids

Time period: From 1-3 days post surgery
Allowed foods:
Water, non carbonated, decaffeinated and no added sugar drinks, fresh strained juices, strained soups, jelly, mint/green tea and strained herbal drinks.

How to consume
Drink liquids - 30 ml (6 tea spoons) every 15 minutes and ensure the intake of 2-3 liters/day

Remember:
- Avoid sweetened drinks/juices
- Avoid soft drinks and alcohols
- Avoid chewing gum and chocolate
- Don't use a straw to drink liquids
- Stop drinking when you feel full
- Liquids should be served at room temperature

Stage (2): Full fluids (low in fat and simple sugars)

Time period: Two weeks

Allowed foods:
- Low fat (milk, laban, and yogurt)
- Custard made with low fat milk (no added sugar).
- Fresh juices with no added sugar.

How to consume

6 meals daily ; each one containing 120 ml (1/2 cup taken within half an hour)

Note:

In addition to these fluids you should continue to drink a sufficient amount of clear fluids (1-2) liters daily (30 ml every 15 minutes)

2nd stage menu

Example of a meal for one day meal

Time		Meal
From	To	
7:00	7:30	Low fat milk or semolina porridge
7:30	9:30	Clear liquids/30 ml every 15 minutes
9:30	10:00	Custard
10:00	12:00	Clear liquids/30 ml every 15 minutes
12:00	1:00	Unsweetened jelly, low fat milk or laban, strained soups
1:00	3:00	30 ml every 15 minutes
3:00	3:30	Rice pudding or custard or tea with milk
3:30	6:00	Clear liquids/30 ml every 15 minutes
6:00	7:00	Unsweetened jelly, low fat milk or laban, strained soups

Post Bariatric Surgery Diet

4

Stage(3): Pureed foods

Time period: 2-4 weeks

Allowed foods:

- Low fat labnah
- Low fat soft cheese (cottage/cream cheese)
- Boiled egg (or scrambled with a little oil)
- Pureed/cooked vegetables (without skins or seeds)
- Pureed fruit (without skins or seeds)
- Pureed meat/fish/chicken
- Commercial food, prepared specially for babies

How to consume

4-5 meals daily ; each one containing 90- 120 gm (6-8 tablespoons)
Each meal to be consumed within a period of half an hour
At least three of your meals should contains protein source (meat/fish/chicken or alternatives such as cheese and labnah)
Continue drinking 1-2 liters of fluids daily (30 ml every 15 minutes)

3rd stage menu (Example of one day meal)

Time	Meal
7:00 Breakfast	½ cup oatmeal or semolina made with skimmed milk. 1 slice low fat cheese or 30 g cottage cheese/ labnah.
9:00	½ -1 cup low fat/skimmed milk; sip slowly (4 Tablespoons)/15 minutes.
10:00	½ cup clear fluid; sipped slowly (4 tablespoons)/15 minutes.
11:00	3 tablespoons low fat cheese/labnah.
12:00	½ cup fresh juice sip slowly (4 tablespoons)/15 minutes.
1:00 Lunch	4 tablespoons pureed lean meat (chicken, fish or turkey).
3:00	½ cup rice pudding or baby's prepared food.
5:00	Clear fluid or fresh juice, sip slowly (4 tablespoons)/15 minutes
6:00-7:00 Dinner	4 tablespoons tuna (preserved in water), or low fat cottage cheese or labnah. ¼ cup pureed vegetables
8:00	½ cup low fat yogurt

Stage 4: Soft foods

Period: 4-6 weeks (depending on the patient's tolerance)

Allowed foods

- Skinless boiled or grilled chicken (minced or chopped)
- Grilled or cooked fish
- Low fat minced meat
- Canned tuna without oil
- Low fat cheese
- A small amount(1/2 cup) of well cooked starches (rice, potato, macaroni)
- White bread (trimmed)
- Soft peeled fruit and vegetables without seeds (banana, apple, papaya, pear, etc.)
- For cooking you can use little amount of oil (2-3 teaspoons)

Number of meals and quantity

Eat 3-4 meals daily. Each meal should contain 30 grams of (meats, fish or chicken) or two tablespoons of labnah or cheese.

4th stage menu Example of one day meal

Time	Meal
7:00 Breakfast	One egg (poached or scrambled) without added fat. ½ cup oatmeal or semolina made with skimmed milk.
8:00	½ cup skimmed milk ½ cup fresh juice Sip slowly ¼ cup/15minutes
9:00	1 cup of clear fluid sip slowly - ¼ cup/15minutes
10:00	Low fat cheese sandwich(2 trimmed slices of bread)
11:00	½ cup mashed fruit (apple, banana, or pear)
12:00	4 tablespoons(60g) well cooked or minced (fish, meat, chicken) ½ cup well cooked ground/minced vegetables ½ cup low fat yogurt.
1:00 Lunch	1 cup clear fluid sip slowly - ¼ cup/15minutes
2:00	½ cup flavored yogurt
3:00	1 plain biscuit or brown rusk with 1 tablespoon of peanut butter
5:00	1 cup clear fluid sip slowly - ¼ cup/15minutes
6:00	4 tablespoons (60g) well cooked or minced (fish, meat, chicken) 2 trimmed bread slices ½ cup well cooked ground/minced vegetables
7:00	½ cup mashed fruit
8:00	½ cup pudding
9:00	½ cup low fat yogurt

Stage 5: Regular food

Solid food is introduced gradually and in small amounts with the food of the previous stages. Work with your dietitian to determine your daily requirements.

Always remember

- Chew food properly.
- You may not tolerate some food items like:
    - Red meat
    - White bread
    - Corn
    - Whole fresh fruit and vegetables (with skin and seeds)
    - Dried fruits.
    - Nuts
- If you develop a food intolerance, try the same food again one or two weeks later
- Consume 1½ liters of water daily (30 - 60 ml every 15 minutes)
- Drink 2 cups of low fat milk or yogurt to get your calcium requirements (60 ml every 15 minutes)
- Don't drink fluids with meals, instead drink half an hour before or after meals